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PRINCIPAL INVESTIGATOR: Mary M. Horowitz, M.D., M.S.

CONTRACTING ORGANIZATION: Medical College of Wisconsin
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13. ABSTRACT *(Maximum 200*

The Autologous Blood and Marrow Transplant Registry - North America (ABMTR) is a voluntary organization of over 180 autotransplant centers that contribute clinical data on consecutive autotransplant recipients to a Statistical Center at the Medical College of Wisconsin. The ABMTR's database includes information for over 8,000 women receiving autotransplants for breast cancer. According to data reported to the ABMTR, breast cancer is the most common indication for blood and marrow transplantation (allogeneic or autologous) in North America. The current contract facilitates numerous enhancements to the ABMTR's clinical database, statistical support services and informational programs. These include collection of additional institutional and socioeconomic data on women receiving autotransplants for breast cancer, streamlining data entry and management, development of appropriate statistical techniques for analyzing posttransplant data and expansion of programs to provide access to collected data for patients, physicians and others involved in caring for women with breast cancer.

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M Adams 11/25/92

PI - Signature Date

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INTRODUCTION

Use of high-dose therapy with autologous blood or bone marrow hematopoietic support (autotransplants) to treat breast cancer is increasing rapidly. According to data reported to the Autologous Blood and Marrow Transplant Registry - North America (ABMTR), breast cancer was the most common indication for allogeneic or autologous blood or marrow transplantation in 1995 (Appendix 4; Figure 2). The ABMTR maintains a large database of clinical information on persons receiving autotransplants. This database has the potential to provide important information relevant to breast cancer treatment. The purpose of the work funded in this contract was 1.) to enhance the existing ABMTR database so that important unresolved issues in use of autotransplants to treat breast cancer could be addressed and to provide accurate information on autotransplants to women with breast cancer; and, 2.) to develop and make available appropriate biostatistical models for analyzing this database. Considerable progress was made during the first year of this contract including development of revised data collection forms, planning an institutional survey, evaluation of statistical models, direct provision of data to patients and clinicians, presentation of data to national societies and organizations involved in planning breast cancer research, and planning of a registry World Wide Web site with information related to autotransplants for breast cancer. Progress continued in the second year of the project including development of software for distributed data entry, initiation and near-completion of the institutional survey planned in Year 1, provision of general transplant and breast cancer information on the World Wide Web, development of a comprehensive review of autotransplants in breast cancer soon to be put on the World Wide Web, and continued work on appropriate statistical models. Progress in each of the Technical Objectives outlined in our contract proposal is outlined below.

PROGRESS IN ACHIEVING TECHNICAL OBJECTIVES

1.0 ***Develop and enhance an observational database for autotransplants in breast cancer, including demographic, clinical, treatment, financial, and outcome data.***

1.1 Data collection

Data collection during for 1994-1996 is summarized in Table 1.1.

Table 1.1

Dates	Core Data	Comprehensive Data
7/94 - 6/95	1,900	637
7/95 - 6/96	1,575	958
TOTAL	3,945	1,595

The ABMTR now has core data for 8,065 and comprehensive data for 2,694 recipients of autotransplants for breast cancer.

Data collection instruments (Report Forms) were revised during the first year of this contract and distributed in August 1995 (Appendix 1). Report Form enhancements included fields for: 1.) income, occupation, educational level, and place of residence of autotransplant recipients; 2.) source and mode of payment for transplant procedure (insurer, fixed fee versus fee for service); 3.) inpatient versus outpatient setting for high-dose treatment; 4.) total number of hospital days in the first 100 days posttransplant; 5.) reason for using bone marrow versus peripheral blood stem cells for hematopoietic support; 6.) additional details regarding prior treatment for breast cancer; 7.) graft procurement procedures. Additionally the forms were made clearer, incorporating more detailed explanations for data required, and formatted so that data entry could be done directly from the Forms without an intermediate coding step. During the second year of the Contract, data entry software was modified to accommodate the new Forms (data entry screens now mirror Report Forms) and data submitted on the previous Forms were converted to the new format. Additionally, we obtained supplemental data for patients previously registered. It was not deemed feasible, based on discussions with data managers at participating hospitals, to obtain socioeconomic information on all previously reported patients but additional data on organ involvement, prior treatment, other disease-related variables and posttransplant secondary cancers were provided for about 2,000 patients. The result of these enhancements is a database with greater capabilities to address multiple issues relevant to breast cancer treatment.

1.2 Uniform Reporting of Data

During the second year of this contract, work began on a revised Data Manual to accompany the new Report Forms. The new manual gives comprehensive explanations of data requested on current forms with examples and suggestions for data sources. Anticipated date of completion is February 1, 1997.

In January 1996, the ABMTR conducted a two-day training session for data managers, in conjunction with the ABMTR Annual Meeting in Keystone, Colorado. The program, attendance list and evaluations for this session are included in Appendix 2. The ABMTR awarded 49 travel grants to partially offset expenses of those attending this session. Revised Report Forms and data collection software were reviewed at this session. Evaluation of the session by the participants indicated a high level of satisfaction with the topics covered and training provided.

1.3 Data Review and Entry

Revised Report Forms have several advantages for the data review and entry process. Forms now minimize open-ended and text-field responses which make completion easier and faster, and provide more precise responses. The new format also eliminates most of the need for coding prior to computer entry, making the data entry process more accurate and efficient. In the second year of this contract, data entry tasks were shifted from an outside contractor to the Statistical Center, where data are now entered by trained Data Entry Assistants who also code the limited number of free text fields. Prior to this, forms were coded by Statistical Center personnel and coding sheets sent out for computer entry.

As noted in Section 1.1, data entry screens now mimic Reporting Forms, which also facilitates accurate data entry. During the second year of the contract, we continued our work with StemCell Technologies to develop software for distributed data entry. Approximately 100 centers have purchased StemSoft and about 15 now use StemSoft programs to enter data and generate (paper) ABMTR forms. More are expected to start using the software for reporting during the next six months. Software to directly convert data entered with StemSoft software to a computerized format appropriate for incorporation in the ABMTR database is being developed in cooperation with StemCell and tested at the ABMTR Statistical Center. Further modifications are required before this software can be widely implemented but, once implemented, it will allow data entry to be done completely at transplant centers, submitted on disk and incorporated into the ABMTR database after appropriate error, consistency and virus checks. This will result in substantial savings in effort and cost by the Statistical Center, allowing us to keep pace with rapidly increasing volumes without substantially increasing data management costs. During the next contract year, the Statistical Center will increase its efforts to implement more extensive error checks into the data entry programs so that centers can correct errors and resolve inconsistencies before data are submitted. Processing paper forms will still be done for those centers who do not purchase StemSoft software. We are still considering the benefits of a bar coding system for tracking Report Forms though the move to a paperless system, even if not adopted by all centers, will substantially decrease the number of paper forms to be tracked. Other options for managing paper forms include scanning and digitizing those images. Images would be reviewed visually on a large screen PC to verify any spots where the software was unsure of the correct interpretation of digits.

1.4 Data validation

An Audit Schema was developed and approved in 1995 (Appendix 3). The plan was to audit 20 randomly selected centers yearly. We actually audited 23 in the past year. The list of centers audited in the past year is shown below.

Date	Institution	Team Leader
December, 1995	Toronto Hospital	Keating
April, 1996	Univ. of Wisconsin - Madison	Longo
May, 1996	Medical College of Wisconsin, Milwaukee	Burns
May, 1996	Montefiore Hospital, Pittsburgh	Ball
June, 1996	Johns Hopkins, Baltimore	Miller
July, 1996	Univ. of Minnesota, Minneapolis	McGlave
July, 1996	Case Western Reserve University	Lazarus
July, 1996	Univ. of Nebraska, Omaha	Armitage
July, 1996	Children's Hosp, Cincinnati	Harris
August, 1996	Hosp for Sick Children, Toronto	Calderwood
August, 1996	Duke University	Kurtzburg
September, 1996	University of Oklahoma	Confer
September, 1996	St. Judes Hospital, Memphis	Brenner
September, 1996	Baylor University, Dallas	Fay
September, 1996	Dana Farber Cancer Institute, Boston	Elias
September, 1996	Royal Victoria Hospital, Montreal	Langleben
September, 1996	Vancouver Hospital	Barnett
September, 1996	St. Louis University	Petruska
October, 1996	NE Ontario Cancer Institute, Sudbury	Gluck
October, 1996	Emory Clinic, Atlanta	Yaeger
November, 1996	Baptist Hospital, Miami	Kalman
November, 1996	H.L. Moffitt Cancer Center, Tampa	Elfenbein
November, 1996	Univ. of Alabama, Birmingham	Vaughan

Results of audits indicate a high level of accuracy in data reporting.

1.5 Computer Capabilities

The color printer purchased in Year 1 is being used to produce high quality graphics for educational and scientific materials (Appendix 4).

During the second year of the contact, the Statistical Center switched from a manual to a computerized log-in system that includes checking key fields on Report Forms against previously submitted Registration Data. During this contract year, many centers started to provide registration data on disk rather than paper. Statistical Center personnel are working on conversion programs to accommodate multiple data formats. As noted above, the move toward replacing paper with paperless systems for registering and reporting data has made the proposed implementation of a bar code system for tracking reports less

urgent. Accordingly we have requested that the funds originally designated for such a system be reassigned to purchase computers for Data Entry Assistants who log in cases and directly enter data from Report Forms and programmers who are developing, testing and implementing software for distributed data entry.

2.0 ***Identify institutional characteristics of centers performing autotransplants for breast cancer in the United States and Canada, including academic affiliation, patient volume, physician training, staff/patient ratio.***

The institutional survey designed in Year 1 was distributed in early 1996. To date, 124 U.S. centers have provided data for the survey (Appendix 5). Identification of new centers and additional requests for data from non-responding centers continue. Analysis is proceeding.

3.0 ***Evaluate and develop statistical models and software for effectively analyzing transplant data.***

Statistical Center faculty have been exploring several aspects of statistical analysis of transplant data. These include the following:

3.1 Estimating the survival function in the proportional hazards regression model: A study of small sample size properties

Dr. John Klein and Prof. Per Andersen (Dept. of Biostatistics, University of Copenhagen) have studied the small sample properties of four asymptotic equivalent estimators of the survival function one obtains from a Cox regression analysis. Included in the study is the performance of the statistics as point estimators as well as their small sample behavior in finding confidence intervals for the survival function.

3.2 Statistical challenges in comparing transplant and non-transplant therapy

Drs. John Klein and Mei-Jie Zhang are studying techniques for improved inference in bone marrow transplant studies. One problem faced when comparing survival under alternative technologies is that the initial reference time origin may be different for each technology. For example, when comparing bone marrow transplants to conventional chemotherapy the clock for transplant starts at transplant while for chemotherapy it may start at some other landmark event. Some adjustment for the different time scales must be made. A study of various approaches found that a left-truncated Cox regression technique provided the optimal means of estimating covariate effects.

3.3 Effects of model misspecification in estimating covariate effects in survival analysis for small sample sizes

Dr. Klein and Drs. Li (University of Pittsburgh) and Moeschberger (Ohio State University) have compared the small sample performance of the Cox regression model as compared to the parametric models available in most statistical packages when the Cox model holds as well as when the assumption of proportional hazards is violated. The study shows that the Cox model is very robust to model misspecification while the other models are not.

3.4 The use of additive hazard regression models in analyzing bone marrow transplant data

Dr. Klein and Ms. Alicia Howell have developed a user friendly SAS macro to fit Aalen's additive regression model to right censored data. This program has been used to study relative performance of the additive and proportional hazards models.

3.5 Confidence regions for the times where two survival curves are different.

Profs. Klein and Zhang have developed a procedure for finding confidence regions for the times at which two treatments have different survival functions. The confidence regions can be based on either a proportional hazards or additive hazards model. They allow for adjustment for other fixed covaiates.

3.6 Comparison of tests for center effects.

Drs. Klein, Zhang and Per Andersen (University of Copenhagen) have completed an extensive Monte Carlo study of methods of testing for the presence of a center effect in a Cox regression analysis. They compared the performance of a fixed covariate approach to modeling the center effect to a score test for a random center. The study found that the fixed effect test rejects the hypothesis of no center effect too often when there is no center effect and that this test requires much larger sample sizes not to be anti-conservative. The random effects test works quite well for small samples and has quite good power to detect either fixed or random group effects. The study also examined the effect of ignoring a center effect on the fixed covariates of interest. The manuscript which describes these results is currently being prepared.

3.7 The use of Frailty (random effect) models in survival analysis

Frailty models are used in survival analysis to either model unobserved heterogeneity or to model shared unobserved random effects between group members (e.g. siblings). For the univariate case Prof. Klein and Prof. Niels Keiding and Per Andersen (University of Copenhagen) have studied the effects of ignoring the frailty when there is a random effect. They found that when the extra homogeneity is ignored the regression coefficients tend to be too small. This effect is somewhat abated if an accelerated failure time model is used in the estimation rather than the proportional hazards model. For the multivariate

frailty problem Dr. Klein and his students are writing user friendly SAS macros to implement the semi-parametric gamma, inverse Gaussian and positive stable frailty models. Estimation in these models is based on recent theoretical work by Drs. Klein and Andersen that estimates the regression coefficients using a modified EM algorithm and which has led to an improved estimator of standard error of the model parameters. Dr. Klein and Laud (MCW Biostatistics) have implemented a fully Baysian approach to the semi-parametric gamma frailty problem. They are now extending this approach to other frailty models. This Baysian approach finds the posterior by using a Monte Carlo Markov chain approach. Profs. Klein and Zhang are investigating an alternative frailty model for the accelerated failure time class of models which leads to a multivariate log normal distribution in each group. They are developing an algorithm for estimation of parameters based on a censored sample form this multivariate log normal model.

3.8 Analyzing longitudinal data

Profs. Zhang and Scheike (Biostatistics Dept., University of Copenhagen) are studying the model identification problem of the regression analysis for longitudinal data with counting process measurement times. Prof. Thomas Scheike studied parametric and nonparametric regression function for longitudinal data. The goodness-of-fit test for model selection is under study.

3.9 Multistate modeling of transplant data

Multistate models are used in survival analysis to model complex experiments where a patient may experience a number of intermediate events prior to their eventual death or treatment failure. Often each of the events is modeled separately and their effects on each other are inferred on an ad hoc basis. Prof. Klein with Prof. Keiding (University of Copenhagen) and Chun-Lin Qian (The American College of Radiology) have examined techniques for synthesizing the many intermediate analyses into a coherent set of summary predictive probabilities. Ongoing work with Klein, Zhang and Keiding is looking at the problem of modeling serial measurements such as blood transfusions in a complex survival experiment such as a bone marrow transplant.

4.0 *Provide access to data and biostatistical support for clinical studies related to autotransplants in breast cancer.*

During the first year of this contract, the ABMTR Working Committee completed its first review of use and outcome of autotransplants for breast cancer. This manuscript is now in press in the *Journal of Clinical Oncology* (Appendix 6). Work is nearly complete on an in-depth analysis of prognostic factors for outcome after autotransplants for metastatic breast cancer and a manuscript will be drafted within the next few months. Other studies in progress are:

4.1. Comparison of autotransplant with conventional chemotherapy for metastatic breast cancer. This analysis uses autotransplant data from the ABMTR and chemotherapy data from the Cancer and Leukemia Group (PI: Don Berry [CALGB], David Hurd [ABMTR]) This latter study will benefit directly from some the statistical work described in section 3.0 and the additional clinical data now available.

4.2. Assessment of variation in costs of autotransplants for breast cancer among institutions. (PI: Charles Bennett, Northwestern University). This study will benefit from the socioeconomic and resource utilization data now collected on Report Forms.

4.3. Analysis of prognostic factors for survival after autotransplants for Stage II, III breast cancer. (PI: Karen Antman, Columbia University). This study will benefit from the additional clinical data now available.

4.4. Determination of second cancer risk after autotransplants for breast cancer. (PI: Mary Horowitz) Increased surveillance for second cancers was part of several efforts at supplemental data collection.

All of these studies are enhanced by the improved data collection, entry and management funded by this contract and by the greater level of detail now available on transplant recipients.

5.0 ***Disseminate information regarding autotransplants for breast cancer to patients, physicians and others involved in care of women with breast cancer.***

The ABMTR database is a unique resource of information regarding use and outcome of transplants, containing data not readily available in the medical literature. Summary statistics on the use and outcome of autotransplants for breast cancer were included in the November 1996 issue of the ABMTR Newsletter (Appendix 7), which is widely distributed to transplant and oncology centers. An updated version of these data are also available on-line at the IBMTR/ABMTR homepage on the World Wide Web (address: www.biostat.mcw.edu/IBMTR; Appendix 7).

There were 22 presentations of ABMTR data related to use and/or outcome of autotransplants for breast cancer during the second contract year (Appendix 8). Notable among these was a presentation on the low risk of transplant-related mortality after autotransplants for breast cancer made by Dr. Horowitz at a meeting of the Blue Cross and Blue Shield Medical Advisory Panel in February, 1996.

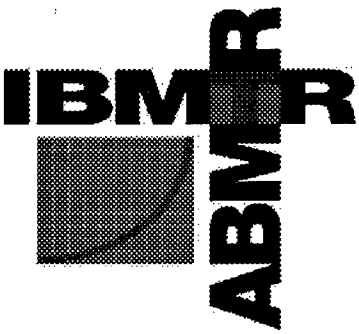
Additionally during the second contract year, the ABMTR, through its Information Resource program (partially funded by this contract) provided information regarding use and outcome of autotransplants for breast cancer in response to about 200 specific requests from physicians, patients and health-related agencies or companies. Data provided in response to these requests often included survival and other outcome data not

readily available in the medical literature. This represents an increase of 300% over the previous calendar year.

In addition to the IBMTR/ABMTR homepage, and in cooperation with the National Marrow Donor Program and the American Society of Blood and Marrow Transplantation, the ABMTR is establishing a World Wide Web site with comprehensive information on the role of transplantation in treating a variety of cancers. A comprehensive review of the role of high-dose chemotherapy in treating breast cancer will be among the first three topics to be made available. Information will be provided at both physician and patient levels, with an extensive bibliography that will be updated periodically, and with links to other relevant Web sites providing information on transplantation and cancer.

CONCLUSIONS AND FUTURE PLANS

This contract continues to facilitate numerous enhancements to the ABMTR database and Statistical Center. It is already elevating the quality of information available for studies and for health care providers and consumers. By completion of the four-year term of this award, we are confident that the infrastructure enhancements will lead to numerous high-quality investigations.



APPENDICES

Grant No. DAMD17-95-1-5002

"Database of Autotransplants for Breast Cancer"

Submitted to: U.S. Army Medical Research and Material Command

December 1, 1996

Autologous Blood & Marrow Transplant Registry - North America
Medical College of Wisconsin
8701 Watertown Plank Road • P.O. Box 26509
Milwaukee, WI 53226 USA

CORE FORM

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

FOR REGISTRY USE ONLY:

I.D. ☐ – ☐☐☐☐ – ☐☐☐☐☐☐

Date received:

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ Month ☐☐ Day ☐☐ Year

Date of report: ☐☐ Month ☐☐ Day ☐☐ Year

IBMTR International Bone Marrow Transplant Registry

Series 095 Reporting Forms

IBMTR/ABMTR

ABMTR North America Autologous Blood & Marrow Transplant Registry

Statistical Center • Medical College of Wisconsin
P.O. Box 26509 • 8701 Watertown Plank Road • Milwaukee, WI 53226
Telephone: 414-456-8325 • Fax: 414-266-8471

Demographics

**** If this is a report of a second (or subsequent) transplant check here ☐ and go to Q.20***

1. Institutional protocol number *(if applicable)*: ☐☐☐☐☐☐☐☐☐☐

2. Was patient enrolled in cooperative group (eg. CALGB, CCSG, EBMT, ECOG, EORTC, MRC, NSABP, POG, SWOG, etc.) study at any time or reported to the NMDP or EBMT? (*include transplant and non-transplant studies*)

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

Study 1: **3.** Group _____ **4.** Study No. _____ **5.** Patient No. _____

Study 2: **6.** Group _____ **7.** Study No. _____ **8.** Patient No. _____

Study 3: **9.** Group _____ **10.** Study No. _____ **11.** Patient No. _____

12. Sex: 1 ☐ Male 2 ☐ Female

13. Race: (*If patient's parents are from two separate groups of the following, check both*)

Caucasian/White
- 11 ☐ European or Western Russia
- 12 ☐ Middle East or North Coast of Africa
- 10 ☐ White, not otherwise specified

Black
- 21 ☐ African American
- 22 ☐ African Black (both parents born in Africa)
- 23 ☐ Caribbean Black
- 24 ☐ South or Central American Black
- 20 ☐ Black, not otherwise specified

Asian/Pacific Islander
- 31 ☐ Asian Indian
- 32 ☐ Filipino
- 33 ☐ Hawaiian (Polynesian)
- 34 ☐ Japanese
- 35 ☐ Korean
- 36 ☐ Northern Chinese
- 37 ☐ Southeast Asian/ Southern Chinese
- 30 ☐ Oriental, not otherwise specified

Hispanic
- 41 ☐ Caribbean Hispanic
- 42 ☐ Mexican or Southwestern USA Hispanic
- 43 ☐ South or Central American Hispanic
- 40 ☐ Hispanic, not otherwise specified

Native American
- 51 ☐ Native Alaskan/ Eskimo/Aleut
- 52 ☐ American Indian
- 50 ☐ Native American, not otherwise specified

Other
- 90 ☐ Other, specify: _____
- 88 ☐ Unknown

14. Date of birth: ☐☐ Month ☐☐ Day ☐☐ Year

TEAM | | | | | IUBMID | | | | | | |

Disease

15. What was the primary disease for which transplant was performed?
(*Appropriate Insert must be submitted with this form*)

10 ☐ Acute myelogenous leukemia (AML or ANLL)
- 11 ☐ M1, myeloblastic
- 12 ☐ M2, myelocytic
- 13 ☐ M3, promyelocytic (APML, APL)
- 14 ☐ M4, myelomonocytic
- 15 ☐ M5, monocytic
- 16 ☐ M6, erythroblastic
- 17 ☐ M7, megakaryoblastic
- 18 ☐ Granulocytic sarcoma
- 19 ☐ Other, specify: _____
- 10 ☐ Unknown

Complete Insert I and continue with Question 17 on Page 5

20 ☐ Acute lymphoblastic leukemia (ALL)
- 21 ☐ Mature B-cell (L3)
- 22 ☐ T-cell
- 23 ☐ Null cell (early Pre-B)
- 24 ☐ cALLa (includes Pre-B)
- 29 ☐ Other, specify: _____
- 20 ☐ Unknown

Complete Insert II and continue with Question 17 on Page 5

40 ☐ Chronic myelogenous leukemia (CML)
- 41 ☐ Ph^1 +; BCR/ABL+
- 42 ☐ Ph^1 +; BCR/ABL -
- 43 ☐ Ph^1 +; BCR/ABL unknown
- 44 ☐ Ph^1 -; BCR/ABL +
- 45 ☐ Ph^1 -; BCR/ABL -
- 46 ☐ Ph^1 -; BCR/ABL unknown
- 47 ☐ Ph^1 unknown; BCR/ABL +
- 48 ☐ Ph^1 unknown; BCR/ABL -
- 49 ☐ Other, specify: _____
- 40 ☐ Ph^1 unknown; BCR/ABL unknown

Complete Insert III and continue with Question 17 on Page 5

30 ☐ Other leukemia
- 34 ☐ Chronic lymphocytic leukemia (CLL)

Complete Insert IV and continue with Question 17 on Page 5

- 31 ☐ Acute undifferentiated leukemia
- 32 ☐ Biphenotypic, bilineage or hybrid leukemia
- 33 ☐ Acute mast cell leukemia
- 35 ☐ Hairy cell leukemia
- 36 ☐ Juvenile CML (no evidence of Philadelphia chromosome or BCR/ABL)
- 37 ☐ Prolymphocytic leukemia (PLL)
- 38 ☐ M0, stem cell
- 39 ☐ Other, specify: _____
- 30 ☐ Unknown

Continue with Question 16 on Page 5

50 ☐ Myelodysplastic/ myeloproliferative disorders (*please classify all preleukemias*)

(*If patient has transformed to AML, complete Insert I and indicate AML as the primary disease*)
- 51 ☐ Refractory anemia (RA)
- 52 ☐ Refractory anemia with excess blasts (RAEB)
- 53 ☐ Refractory anemia with excess blasts in transformation (RAEBT)
- 54 ☐ Chronic myelomonocytic leukemia (CMML)
- 55 ☐ Acquired idiopathic sideroblastic anemia (RARS)
- 56 ☐ Paroxysmal nocturnal hemoglobinuria (PNH)
- 57 ☐ Polycythemia vera
- 58 ☐ Essential or primary thrombocythemia
- 59 ☐ Myelofibrosis with myeloid metaplasia
- 60 ☐ Other myelofibrosis or myelosclerosis
- 69 ☐ Other myelodysplasia or myeloproliferative disorder, specify: _____
- 50 ☐ Unknown

Complete Insert V and continue with Question 17 on Page 5

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

100 ☐ Non-Hodgkin lymphoma
- 101 ☐ Small cell lymphocytic
- 102 ☐ Follicular, predominantly small cleaved cell
- 103 ☐ Follicular, mixed, small cleaved and large cell
- 104 ☐ Follicular, predominantly large cell
- 105 ☐ Diffuse, small cleaved cell
- 106 ☐ Diffuse, mixed, small and large cell
- 107 ☐ Diffuse, large cell
- 108 ☐ Large cell, immunoblastic
- 109 ☐ Lymphoblastic
- 110 ☐ Small noncleaved cell, unclassified
- 111 ☐ Small noncleaved cell, Burkitt
- 112 ☐ Small noncleaved cell, non-Burkitt
- 113 ☐ Mycosis fungoides
- 114 ☐ Histiocytic
- 115 ☐ Mantle cell/ intermediate differentiation
- 116 ☐ Composite, specify: _____
- 117 ☐ Large cell anaplastic lymphoma, Ki1 positive
- 118 ☐ Primary CNS lymphoma
- 119 ☐ Other non-Hodgkin lymphoma, specify: _____
- 100 ☐ Non-Hodgkin lymphoma, unknown

Complete Insert VI and continue with Question 17 on Page 5

150 ☐ Hodgkin lymphoma
- 151 ☐ Lymphocyte predominant
- 152 ☐ Nodular sclerosis
- 153 ☐ Mixed cellularity
- 154 ☐ Lymphocyte depleted
- 159 ☐ Other Hodgkin lymphoma, specify: _____
- 150 ☐ Hodgkin lymphoma, unknown

Complete Insert VI and continue with Question 17 on Page 5

170 ☐ Multiple myeloma/ Plasma cell disorder
- 171 ☐ Multiple myeloma

Complete Insert VII and continue with Question 17 on Page 5

- 172 ☐ Plasma cell leukemia
- 173 ☐ Waldenstrom macroglobulinemia
- 174 ☐ Amyloidosis
- 175 ☐ Solitary plasmacytoma
- 179 ☐ Other, specify: _____

Continue with Question 16 on Page 5

200 ☐ Other malignancies
- 250 ☐ Breast cancer

Complete Insert VIII and continue with Question 17 on Page 5

- 201 ☐ Head & neck cancer
- 202 ☐ Lung cancer, small cell
- 203 ☐ Lung cancer, non-small cell
- 239 ☐ Lung, not otherwise specified
- 204 ☐ Mediastinal neoplasm, specify: _____
- 205 ☐ GI tract cancer
- 206 ☐ Pancreatic cancer
- 207 ☐ Hepatobiliary cancer
- 208 ☐ Kidney & urinary tract cancer
- 209 ☐ Prostate cancer
- 210 ☐ Testicular cancer
- 211 ☐ External genitalia cancer
- 212 ☐ Cervical cancer
- 213 ☐ Uterine cancer
- 214 ☐ Ovarian (epithelial) cancer
- 215 ☐ Vaginal cancer
- 216 ☐ Sarcoma unspecified
- 217 ☐ Soft tissue sarcoma
- 218 ☐ Bone sarcoma (not Ewing)
- 219 ☐ Melanoma
- 220 ☐ Central nervous system tumor
- 221 ☐ Wilm tumor
- 222 ☐ Neuroblastoma
- 223 ☐ Retinoblastoma
- 224 ☐ Ewing sarcoma
- 269 ☐ Other malignancy, specify: _____

Continue with Question 16 on Page 5

300 ☐ Severe aplastic anemia
- 301 ☐ Idiopathic
- 302 ☐ Secondary to hepatitis
- 303 ☐ Secondary to toxin/other drug
- 304 ☐ Amegakaryocytosis (not congenital)
- 309 ☐ Other, specify: _____

Complete Insert IX and continue with Question 17 on Page 5

310 ☐ Inherited abnormalities of erythrocyte differentiation or function

(If patient has developed leukemia, complete Insert for appropriate leukemia diagnosis)
- 311 ☐ Fanconi anemia

Complete Insert X and continue with Question 17 on Page 5

- 312 ☐ Diamond-Blackfan anemia (pure red cell aplasia)
- 319 ☐ Other, specify: _____

Complete Insert IX and continue with Question 17 on Page 5

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310 ☐ Inherited abnormalities of erythrocyte differentiation or function, *continued*

- 350 ☐ Thalassemia major (β thalassemia), unspecified
- 351 ☐ Type A Thalassemia major
- 352 ☐ Type B+ Thalassemia major
- 353 ☐ Type B0 Thalassemia major
- 354 ☐ Type BE Thalassemia major
- 355 ☐ Sickle Thalassemia major
- 356 ☐ Sickle cell anemia
- 359 ☐ Other hemoglobinopathy, specify: _____
- 310 ☐ Unknown

Complete Insert XI and continue with Question 17 on Page 5

400 ☐ SCID and other disorders of the immune system

- 401 ☐ ADA deficiency severe combined immunodeficiency (SCID)
- 402 ☐ Absence of T and B cells SCID
- 403 ☐ Absence of T, normal B cell SCID
- 404 ☐ Omenn syndrome
- 405 ☐ Reticular dysgenesis
- 406 ☐ Bare lymphocyte syndrome
- 419 ☐ SCID other, specify: _____
- 451 ☐ Ataxia telangiectasia
- 452 ☐ HIV infection
- 454 ☐ DiGeorge anomaly
- 455 ☐ Chronic granulomatous disease
- 456 ☐ Chediak-Higashi syndrome
- 457 ☐ Common variable immunodeficiency
- 458 ☐ X-linked lymphoproliferative syndrome
- 459 ☐ Leukocyte adhesion deficiencies, including GP180, CD-18, LFA and WBC adhesion deficiencies
- 460 ☐ Kostmann agranulocytosis (congenital neutropenia)
- 461 ☐ Neutrophil actin deficiency
- 462 ☐ Cartilage-hair hypoplasia
- 470 ☐ Combined immunodeficiency disease (CID), unspecified
- 474 ☐ CID other, specify: _____
- 479 ☐ Other immunodeficiencies, specify: _____

Complete Insert XII and continue with Question 17 on Page 5

- 453 ☐ Wiskott Aldrich syndrome

Complete Insert XIII and continue with Question 17 on Page 5

500 ☐ Inherited abnormalities of platelets

- 501 ☐ Amegakaryocytosis/ congenital thrombocytopenia
- 502 ☐ Glanzmann thrombasthenia
- 509 ☐ Other, specify: _____

Continue with Question 16 on Page 5

520 ☐ Inherited disorders of metabolism

- 521 ☐ Osteopetrosis (malignant infantile osteopetrosis)

Complete Insert XV and continue with Question 17 on Page 5

- 522 ☐ Lesch-Nyhan

Mucopolysaccharidosis

- 531 ☐ Hurler syndrome (IH)
- 532 ☐ Scheie syndrome (IS)
- 533 ☐ Hunter syndrome (II)
- 534 ☐ Sanfilippo (III)
- 535 ☐ Morquio (IV)
- 536 ☐ Maroteaux-Lamy (VI)
- 537 ☐ β-glucuronidase deficiency (VII)
- 538 ☐ Mucopolysaccharidosis (V)
- 539 ☐ Other mucopolysaccharidosis, specify: _____
- 530 ☐ Mucopolysaccharidosis, not otherwise specified

Mucolipidoses

- 541 ☐ Gaucher disease
- 542 ☐ Metachromatic leukodystrophy
- 543 ☐ Adrenoleukodystrophy
- 544 ☐ Krabbe disease (globoid leukodystrophy)
- 545 ☐ Neiman-Pick disease
- 546 ☐ I-cell disease
- 547 ☐ Wolman disease
- 548 ☐ Glucose storage disease
- 549 ☐ Lysosomal storage disease
- 559 ☐ Other mucolipidoses, specify: _____
- 540 ☐ Mucolipidoses, not otherwise specified
- 529 ☐ Other specific inherited metabolic disorders, specify: _____
- 520 ☐ Unknown

Complete Insert XIV and continue with Question 17 on Page 5

570 ☐ Histiocytic disorders

- 571 ☐ Familial erythrophagocytic lymphohistiocytosis (FEL, Familial hemophagocytic lymphohistiocytosis)
- 572 ☐ Histiocytosis-X
- 573 ☐ Hemophagocytosis
- 574 ☐ Malignant histiocytosis
- 579 ☐ Other, specify: _____
- 570 ☐ Unknown

Continue with Question 16 on Page 5

900 ☐ Other

Specify: _____

Continue with Question 16 on Page 5

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Clinical Status of Patient Prior to Conditioning

16. Date of diagnosis of primary disease: *(complete only if a disease-specific Insert is not required)* ☐☐ Month ☐☐ Day ☐☐ Year

17. ***Allografts only:*** Patient's blood type:

1 ☐	A Positive	5 ☐	A Negative	9 ☐	A Rh unknown	88 ☐	Unknown
2 ☐	B Positive	6 ☐	B Negative	10 ☐	B Rh unknown		
3 ☐	AB Positive	7 ☐	AB Negative	11 ☐	AB Rh unknown		
4 ☐	O Positive	8 ☐	O Negative	12 ☐	O Rh unknown		

18. Has patient ever been pregnant?

1 ☐ Yes — **19.** Number of pregnancies: ☐☐
0 ☐ No
8 ☐ Unknown
7 ☐ Not applicable (patient is male, or a female child)

20. Did patient receive blood transfusions at any time prior to conditioning?

1 ☐ Yes — **21.** Give number (best estimate) of donor exposures:

1 ☐	1 - 5	5 ☐	31 - 40
2 ☐	6 - 10	6 ☐	41 - 50
3 ☐	11 - 20	7 ☐	> 50
4 ☐	21 - 30	8 ☐	Unknown

0 ☐ No
8 ☐ Unknown

22. What was the functional status of patient prior to conditioning?

If the patient is 16 years of age or older, complete the Karnofsky Scale. If patient is younger than 16 years of age, complete the Lansky Scale. Rate activity of patient immediately prior to initiation of conditioning.

Karnofsky Scale (age ≥16 yrs)

Select the phrase in the Karnofsky Scale which best describes the activity status of the patient:

Able to carry on normal activity; no special care is needed.
- ☐ 100 Normal; no complaints; no evidence of disease
- ☐ 90 Able to carry on normal activity
- ☐ 80 Normal activity with effort

Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.
- ☐ 70 Cares for self; unable to carry on normal activity or to do active work
- ☐ 60 Requires occasional assistance but is able to care for most needs
- ☐ 50 Requires considerable assistance and frequent medical care

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.
- ☐ 40 Disabled; requires special care and assistance
- ☐ 30 Severely disabled; hospitalization indicated, although death not imminent
- ☐ 20 Very sick; hospitalization necessary
- ☐ 10 Moribund; fatal process progressing rapidly

Lansky Scale (age <16 yrs)

Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the patient:

Normal range.
- ☐ 100 Fully active
- ☐ 90 Minor restriction in physically strenuous play
- ☐ 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction.
- ☐ 70 Both greater restrictions of, and less time spent in, active play
- ☐ 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play

Moderate to severe restriction.
- ☐ 40 Able to initiate quiet activities
- ☐ 30 Needs considerable assistance for quiet activity
- ☐ 20 Limited to very passive activity initiated by others (i.e., TV)
- ☐ 10 Completely disabled, not even passive play

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23. Was there clinically significant coexisting disease or organ impairment prior to conditioning?

1 ☐ Yes
0 ☐ No

What were the diagnoses?

	Yes	No	
24.	1☐	0☐	Significant *hemorrhage* (e.g. CNS or GI), specify site(s): _____
			Cardiovascular
25.	1☐	0☐	Coronary artery disease
26.	1☐	0☐	Hypertension
27.	1☐	0☐	Other cardiac disease, specify: _____
			Endocrine
28.	1☐	0☐	Diabetes mellitus
29.	1☐	0☐	Thyroid disease
30.	1☐	0☐	Other endocrine disease, specify: _____
			CNS
31.	1☐	0☐	Seizure disorder
32.	1☐	0☐	Other CNS disease, specify: _____
			Pulmonary
33.	1☐	0☐	Asthma
34.	1☐	0☐	Other pulmonary disease, specify: _____
35.	1☐	0☐	*Genitourinary* disease, specify: _____
36.	1☐	0☐	*Gastrointestinal* disease, specify: _____
37.	1☐	0☐	*Hematologic* disease, specify: _____
			Chromosomal
38.	1☐	0☐	Fanconi anemia
39.	1☐	0☐	Down syndrome
40.	1☐	0☐	Other chromosomal disorders, specify: _____
41.	1☐	0☐	History of *other malignancy*, specify: _____
42.	1☐	0☐	*Neonatal GVHD*
			Autoimmune disease
43.	1☐	0☐	Rheumatoid arthritis
44.	1☐	0☐	Systemic lupus erythematosis
45.	1☐	0☐	Multiple sclerosis
46.	1☐	0☐	Polyarteritis nodosa
47.	1☐	0☐	Psoriasis
48.	1☐	0☐	Other autoimmune disease, specify: _____
49.	1☐	0☐	*Other*, specify: _____

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Organ Function Prior to Conditioning

Provide values for patient's liver function just prior to conditioning:

		Date tested: Month Day Year	What is the upper limit of normal for your institution?
50. AST (SGOT)	[ ][ ][ ] . U/L	**51.** [ ][ ] [ ][ ] [ ][ ]	**52.** [ ][ ][ ] . U/L
53. ALT (SGPT)	[ ][ ][ ] . U/L	**54.** [ ][ ] [ ][ ] [ ][ ]	**55.** [ ][ ][ ] . U/L
56. Total serum bilirubin	[ ][ ][ ] . [ ]	**58.** [ ][ ] [ ][ ] [ ][ ]	**59.** [ ][ ][ ] . [ ]

57. Unit of measurement for bilirubin:
1 ❑ mg/dL 2 ❑ μmol/L

60. LDH	[ ][ ][ ][ ][ ] . U/L	**61.** [ ][ ] [ ][ ] [ ][ ]	**62.** [ ][ ][ ][ ] . U/L

63. Did patient have known clinical liver disease (eg. viral hepatitis) at any time prior to conditioning?

1 ❑ Yes
0 ❑ No

	Yes	No	Unknown	
64.	1 ❑	0 ❑	8 ❑	Hepatitis B
65.	1 ❑	0 ❑	8 ❑	Hepatitis A
66.	1 ❑	0 ❑	8 ❑	Hepatitis C
67.	1 ❑	0 ❑	8 ❑	Drug toxicity
68.	1 ❑	0 ❑	8 ❑	Other, specify: _____

69. Date of onset: [ ][ ] [ ][ ] ❑ Date Unknown
Month Year

70. What was patient's serum creatinine prior to conditioning? [ ][ ][ ] . [ ]

71. Unit of measurement for creatinine:
1 ❑ mg/dL 2 ❑ μmol/L

72. Date tested: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

73. Patient smokes cigarettes, or has in the past:

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

74. Average number of packs per day: [ ] . [ ]

75. Number of years: [ ][ ]

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76. Was clinically important infection(s) present or being treated within one week prior to conditioning?
Note: Report later infections on page 30 of this report.

1 ☐ Yes
0 ☐ No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism were involved, list one site of infection and organism on the first line, second site and/or organism on second line.

		Site	Organism
77. ☐ Bacterial Typical	First	**78.** ☐☐	**79.** _____
	Second	**80.** ☐☐	**81.** _____
Atypical	First	**83.** ☐☐	**84.** B☐☐☐
	Second	**85.** ☐☐	**86.** B☐☐☐
		87. Other atypical bacterium, specify: _____	
88. ☐ Fungal	First	**89.** ☐☐	**90.** F☐☐☐
	Second	**91.** ☐☐	**92.** F☐☐☐
		93. Other fungus, specify: _____	
94. ☐ Viral	First	**95.** ☐☐	**96.** V☐☐☐
	Second	**97.** ☐☐	**98.** V☐☐☐
		99. Other virus, specify: _____	
100. ☐ Parasitic	First	**101.** ☐☐	**102.** P☐☐☐
	Second	**103.** ☐☐	**104.** P☐☐☐
		105. Other parasite, specify: _____	
106. ☐ No organism identified	First	**107.** ☐☐	**108.** O509
	Second	**109.** ☐☐	**110.** O509

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Codes for Common Sites of Infection

01 Blood/buffy coat
02 Disseminated – generalized, isolated at 3 or more distinct sites
03 *Central Nervous System unspecified*
04 Brain
05 Spinal cord
06 Meninges and CSF
10 *Gastrointestinal Tract unspecified*
11 Lips
12 Tongue, oral cavity and oro-pharynx
13 Esophagus
14 Stomach
15 Gallbladder and biliary tree (not hepatitis), pancreas
16 Small intestine
17 Large intestine
18 Feces/stool
19 Peritoneum
20 Liver
30 *Respiratory unspecified*
31 Upper airway and nasopharynx
32 Laryngitis/larynx
33 Lower respiratory tract (lung)
34 Pleural cavity, pleural fluid
35 Sinuses
40 *Genito-Urinary Tract unspecified*
41 Kidneys, renal pelvis, ureters and bladder
42 Prostate
43 Testes
44 Fallopian tubes, uterus, cervix
45 Vagina
50 *Skin unspecified*
51 Genital area
52 Cellulitis
53 Herpes Zoster
54 Rash, pustules or abscesses not typical of any of the above
60 Central venous catheter, not otherwise specified
61 Catheter insertion site
62 Catheter tip
70 Eyes
75 Ear
80 *Other unspecified*
81 Joints
82 Bone marrow
83 Bone cortex (osteomyelitis)
84 Muscle (excluding cardiac)
85 Cardiac (endocardium, myocardium, pericardium)
86 Lymph nodes
87 Spleen

Codes for Commonly Reported Organisms

1. Bacteria

(Indicate code for atypical bacteria; list bacterium for non-atypical bacteria.)

100 Atypical bacteria, not otherwise specified
101 Coxiella
102 Legionella
103 Leptospira
104 Listeria
105 Mycoplasma
106 Nocardia
107 Rickettsia
110 Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
111 Typical tuberculosis (TB, Tuberculosis)
112 Mycobacteria (avium, bovium, intracellulare)
113 Chlamydia
119 Other atypical bacteria, specify

2. Fungal Infections

200 Candida, not otherwise specified
201 Candida albicans
202 Candida krusei
203 Candida parapsilosis
204 Candida tropicalis
205 Torulopsis glabrata (a subspecies of candida)
209 Candida, other
210 Aspergillus, not otherwise specified
211 Aspergillus flavus
212 Aspergillus fumigatus
213 Aspergillus niger
219 Aspergillus, other
220 Cryptococcus species
230 Fusarium species
240 Mucormycosis (zygomycetes, rhizopus)
250 Yeast, not otherwise specified
259 Other fungus, specify

3. Viral Infections

301 Herpes Simplex (HSV1, HSV2)
302 Herpes Zoster (Chicken pox, Varicella)
303 Cytomegalovirus (CMV)
304 Adenovirus
305 Enterovirus (Coxsackie, Echo, Polio)
306 Hepatitis A (HAV)
307 Hepatitis B (HBV, Australian antigen)
308 Hepatitis C (HCV)
309 HIV-1 (HTLV-III)
310 Influenza
311 Measles (Rubeola)
312 Mumps
313 Papovavirus
314 Respiratory syncytial virus (RSV)
315 Rubella (German Measles)
316 Parainfluenza
317 Human herpesvirus-6 (HHV-6)
318 Epstein-Barr virus (EBV)
319 Polyomavirus
320 Rotavirus
321 Rhinovirus
329 Other viral, specify

4. Parasite Infections

401 Pneumocystis (PCP)
402 Toxoplasma
403 Giardia
404 Cryptosporidium
409 Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

5. Other Infections

509 No organism identified

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112. Did patient have a history of clinically important fungal infection at any time prior to conditioning for transplant?

1 ❑ Yes
0 ❑ No

113. Date of onset: ☐☐ ☐☐ (Month Year)

114. Select organism from list on previous page: F☐☐☐ If other, specify: _____

Select site(s) from list on previous page:

115. ☐☐ **116.** ☐☐ Other, specify: _____

Tests for Serological Evidence of Prior Viral Exposure / Infection

	Positive	Negative	Inconclusive	Not Tested
117. HTLV1 antibody	1 ❑	2 ❑	3 ❑	4 ❑
118. Toxoplasma antibody	1 ❑	2 ❑	3 ❑	4 ❑
119. Cytomegalovirus antibody	1 ❑	2 ❑	3 ❑	4 ❑
120. Epstein-Barr antibody	1 ❑	2 ❑	3 ❑	4 ❑
121. Hepatitis B surface and/or core antibody	1 ❑	2 ❑	3 ❑	4 ❑
122. Hepatitis B surface antigen	1 ❑	2 ❑	3 ❑	4 ❑
123. Hepatitis C antibody	1 ❑	2 ❑	3 ❑	4 ❑
124. Hepatitis A antibody	1 ❑	2 ❑	3 ❑	4 ❑
125. Human Immunodeficiency Virus (HIV) antibody	1 ❑	2 ❑	3 ❑	4 ❑

7 ❑ Not able to release information for HIV

High-Dose Therapy (Pretransplant Conditioning)

126. Was patient given high-dose therapy (conditioning) as an inpatient?

1 ❑ Yes
0 ❑ No, given as outpatient
7 ❑ No high dose therapy given

127. Was patient treated in an isolation room during the peri-transplant period?

1 ❑ Yes
0 ❑ No

Please specify:

	Yes	No	
128.	1 ❑	0 ❑	Conventional private room
129.	1 ❑	0 ❑	Laminar air flow room
130.	1 ❑	0 ❑	HEPA filtered room
131.	1 ❑	0 ❑	Positive pressure
132.	1 ❑	0 ❑	Other, specify: _____

133. Date pretransplant conditioning (radiation or drugs) was begun: ☐☐ ☐☐ ☐☐ (Month Day Year)

134. Height at initiation of pretransplant conditioning (without shoes): ☐☐☐ cm

135. Weight at initiation of pretransplant conditioning (without shoes): ☐☐☐ kg

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136. Was irradiation performed as part of the pretransplant conditioning regimen? 1 ☐ Yes 0 ☐ No — Go to Q. 182

137. Source of x-ray therapy:
1 ☐ Linear accelerator 2 ☐ ^{60}Co 7 ☐ Other, specify: _____

138. Maximum energy: ☐☐☐ MV (million volts)

139. Calculated mid-line dose-rate during irradiation: ☐☐.☐ cGy (rad)/min

What was the radiation field?

140. Total Body Radiation 1 ☐ Yes 0 ☐ No

141. Total dose: ☐☐☐☐ cGy

Prescription point:

	Yes	No	
142.	1 ☐	0 ☐	Midline umbilicus
143.	1 ☐	0 ☐	Other, specify: _____

Patient orientation:

	Yes	No	
144.	1 ☐	0 ☐	AP/PA
145.	1 ☐	0 ☐	Other, specify: _____

Method of dose verification:

	Yes	No	
146.	1 ☐	0 ☐	Phantom
147.	1 ☐	0 ☐	Diodes on patient
148.	1 ☐	0 ☐	Other, specify: _____

149. Starting date: ☐☐ ☐☐ ☐☐ (Month Day Year)

150. Was radiation fractionated?
1 ☐ Yes
0 ☐ No
8 ☐ Unknown

If Yes:
151. Dose per fraction: ☐☐☐☐ cGy
152. Number of days: ☐☐
153. Total number of fractions: ☐☐

154. Was shielding used?
1 ☐ Yes
0 ☐ No
8 ☐ Unknown

If Yes:

	Yes	No	
155.	1 ☐	0 ☐	Lungs
156.	1 ☐	0 ☐	Eyes
157.	1 ☐	0 ☐	Liver
158.	1 ☐	0 ☐	Kidney
159.	1 ☐	0 ☐	Other, specify: _____

Radiation field data continued on next page

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160. Total lymphoid or nodal regions 1 ❑ Yes 0 ❑ No

161. Total dose: ☐☐☐☐ cGy **162.** Starting date: ☐☐ Month ☐☐ Day ☐☐ Year

163. Was radiation fractionated?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

164. Dose per fraction: ☐☐☐☐ cGy

165. Number of days: ☐☐

166. Total number of fractions: ☐☐

167. Thoraco-abdominal region 1 ❑ Yes 0 ❑ No

168. Total dose: ☐☐☐☐ cGy **169.** Starting date: ☐☐ Month ☐☐ Day ☐☐ Year

170. Was radiation fractionated?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

171. Dose per fraction: ☐☐☐☐ cGy

172. Number of days: ☐☐

173. Total number of fractions: ☐☐

174. Other radiation field 1 ❑ Yes 0 ❑ No

175. Specify field: _____

176. Total dose: ☐☐☐☐ cGy **177.** Starting date: ☐☐ Month ☐☐ Day ☐☐ Year

178. Was radiation fractionated?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

179. Dose per fraction: ☐☐☐☐ cGy

180. Number of days: ☐☐

181. Total number of fractions: ☐☐

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182. Was (additional) radiation given to other sites?

1 ❑ Yes — 0 ❑ No

183. Was CNS irradiation performed?
1 ❑ Yes — 0 ❑ No — **184.** Dose: ☐☐☐☐ cGy — **185.** Date started: ☐☐ Month ☐☐ Day ☐☐ Year

186. Was gonadal irradiation performed?
1 ❑ Yes — 0 ❑ No — **187.** Dose: ☐☐☐☐ cGy — **188.** Date started: ☐☐ Month ☐☐ Day ☐☐ Year

189. Was splenic irradiation performed?
1 ❑ Yes — 0 ❑ No — **190.** Dose: ☐☐☐☐ cGy — **191.** Date started: ☐☐ Month ☐☐ Day ☐☐ Year

192. Other site, specify: _____
1 ❑ Yes — 0 ❑ No — **193.** Dose: ☐☐☐☐ cGy — **194.** Date started: ☐☐ Month ☐☐ Day ☐☐ Year

195. Were drugs given for pretransplant conditioning? 1 ❑ Yes 0 ❑ No — Go to Q. 361

196. Date started: ☐☐ Month ☐☐ Day ☐☐ Year

	Drug Given No	Drug Given Yes		Total dose (in mg) pre-marrow infusion (not daily dose)	Number of doses	Continuous infusion Yes	Continuous infusion No	Number of days
197. ALG, ALS, ATG, ATS	0 ❑	1 ❑	**198.**	☐☐☐☐☐	**199.** ☐	**200.** 1 ❑	0 ❑	**201.** ☐
202. Anthracycline	0 ❑ No	1 ❑ Yes						
203. Daunomycin	0 ❑	1 ❑	**204.**	☐☐☐☐☐	**205.** ☐	**206.** 1 ❑	0 ❑	**207.** ☐
208. Doxorubicin (Adriamycin)	0 ❑	1 ❑	**209.**	☐☐☐☐☐	**210.** ☐	**211.** 1 ❑	0 ❑	**212.** ☐
213. Idarubicin	0 ❑	1 ❑	**214.**	☐☐☐☐☐	**215.** ☐	**216.** 1 ❑	0 ❑	**217.** ☐
218. Rubidazone	0 ❑	1 ❑	**219.**	☐☐☐☐☐	**220.** ☐	**221.** 1 ❑	0 ❑	**222.** ☐
223. Other anthracycline, specify: _____	0 ❑	1 ❑	**224.**	☐☐☐☐☐	**225.** ☐	**226.** 1 ❑	0 ❑	**227.** ☐
228. Bleomycin	0 ❑	1 ❑	**229.**	☐☐☐☐☐	**230.** ☐	**231.** 1 ❑	0 ❑	**232.** ☐
233. Busulfan (myleran)	0 ❑	1 ❑	**234.**	☐☐☐☐☐	**235.** ☐	**236.** 1 ❑	0 ❑	**237.** ☐
238. Carboplatin	0 ❑	1 ❑	**239.**	☐☐☐☐☐	**240.** ☐	**241.** 1 ❑	0 ❑	**242.** ☐
243. Cisplatin	0 ❑	1 ❑	**244.**	☐☐☐☐☐	**245.** ☐	**246.** 1 ❑	0 ❑	**247.** ☐

Continued on next page

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	Drug Given No	Drug Given Yes	Total dose (in mg) pre-marrow infusion	Number of doses	Continuous infusion	Number of days
248. Corticosteroids (0 ☐ No 1 ☐ Yes)					Yes No	
249. Methylprednisolone (Solumedrol) 1 ☐ Yes — **250.** ☐ Oral ☐ IV			**251.** ☐☐☐☐☐	**252.** ☐	**253.** 1 ☐ 0 ☐	**254.** ☐
0 ☐ No						
255. Prednisone	0 ☐	1 ☐	**256.** ☐☐☐☐☐	**257.** ☐	**258.** 1 ☐ 0 ☐	**259.** ☐
260. Dexamethasone	0 ☐	1 ☐	**261.** ☐☐☐☐☐	**262.** ☐	**263.** 1 ☐ 0 ☐	**264.** ☐
265. Other corticosteroids, specify: _____	0 ☐	1 ☐	**266.** ☐☐☐☐☐	**267.** ☐	**268.** 1 ☐ 0 ☐	**269.** ☐
270. Cyclophosphamide	0 ☐	1 ☐	**271.** ☐☐☐☐☐	**272.** ☐	**273.** 1 ☐ 0 ☐	**274.** ☐
275. Cytarabine (Ara-C)	0 ☐	1 ☐	**276.** ☐☐☐☐☐	**277.** ☐	**278.** 1 ☐ 0 ☐	**279.** ☐
280. Etoposide (VP16)	0 ☐	1 ☐	**281.** ☐☐☐☐☐	**282.** ☐	**283.** 1 ☐ 0 ☐	**284.** ☐
285. Ifosfamide	0 ☐	1 ☐	**286.** ☐☐☐☐☐	**287.** ☐	**288.** 1 ☐ 0 ☐	**289.** ☐
290. Intrathecal chemotherapy (0 ☐ No 1 ☐ Yes)						
291. Cytarabine	0 ☐	1 ☐	**292.** ☐☐☐☐☐	**293.** ☐		**294.** ☐
295. Methotrexate	0 ☐	1 ☐	**296.** ☐☐☐☐☐	**297.** ☐		**298.** ☐
299. Other, specify: _____	0 ☐	1 ☐	**300.** ☐☐☐☐☐	**301.** ☐		**302.** ☐
303. Melphalan (L-PAM) 1 ☐ Yes — **304.** ☐ Oral ☐ IV			**305.** ☐☐☐☐☐	**306.** ☐	**307.** 1 ☐ 0 ☐	**308.** ☐
0 ☐ No						
309. Mitoxantrone	0 ☐	1 ☐	**310.** ☐☐☐☐☐	**311.** ☐	**312.** 1 ☐ 0 ☐	**313.** ☐
314. Monoclonal antibody (0 ☐ No 1 ☐ Yes)						
315. Radionuclide-tagged Mab, specify: _____	0 ☐	1 ☐	**316.** ☐☐☐☐☐	**317.** ☐	**318.** 1 ☐ 0 ☐	**319.** ☐
320. Campath	0 ☐	1 ☐	**321.** ☐☐☐☐☐	**322.** ☐	**323.** 1 ☐ 0 ☐	**324.** ☐
325. Other Mab, specify: _____	0 ☐	1 ☐	**326.** ☐☐☐☐☐	**327.** ☐	**328.** 1 ☐ 0 ☐	**329.** ☐

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	Drug Given No	Drug Given Yes	Total dose (in mg) pre-marrow infusion	Number of doses	Continuous infusion Yes	Continuous infusion No	Number of days
330. Nitrosourea (0 ☐ No 1 ☐ Yes)							
331. BCNU	0 ☐	1 ☐ — **332.**	[ ][ ][ ][ ][ ]	**333.** [ ]	**334.** 1 ☐	0 ☐	**335.** [ ]
336. CCNU	0 ☐	1 ☐ — **337.**	[ ][ ][ ][ ][ ]	**338.** [ ]	**239.** 1 ☐	0 ☐	**340.** [ ]
341. Other nitrosourea, specify: _____	0 ☐	1 ☐ — **342.**	[ ][ ][ ][ ][ ]	**343.** [ ]	**344.** 1 ☐	0 ☐	**345.** [ ]
Paclitaxel (Taxol)	0 ☐	1 ☐ —	[ ][ ][ ][ ][ ]	[ ]	1 ☐	0 ☐	[ ]
346. Teniposide (VM26)	0 ☐	1 ☐ — **347.**	[ ][ ][ ][ ][ ]	**348.** [ ]	**349.** 1 ☐	0 ☐	**350.** [ ]
351. Thiotepa	0 ☐	1 ☐ — **352.**	[ ][ ][ ][ ][ ]	**353.** [ ]	**354.** 1 ☐	0 ☐	**355.** [ ]
356. Other, specify: _____	0 ☐	1 ☐ — **357.**	[ ][ ][ ][ ][ ]	**358.** [ ]	**359.** 1 ☐	0 ☐	**360.** [ ]

361. Was this the first transplant for this recipient?

1 ☐ Yes
0 ☐ No

362. Is a second transplant planned as part of treatment protocol? 1 ☐ Yes 0 ☐ No — Go to Q. 384

363. Number of previous transplants recipient has had: [ ][ ]

(if more than 1 previous transplant, photocopy Q.364–383 and answer for each previous transplant)

Continued on next page

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364. Date of previous transplant: ☐☐ ☐☐ ☐☐
Month Day Year

365. Graft type of previous transplant:

1 ☐ **Autologous**

	Yes	No	
366.	1 ☐	0 ☐	Bone marrow
367.	1 ☐	0 ☐	Peripheral blood
368.	1 ☐	0 ☐	Other, specify: _____

369. Was this transplant reported to the ABMTR – North America?
1 ☐ Yes — ABMTR I.D. ☐☐☐☐☐☐
0 ☐ No
8 ☐ Unknown

2 ☐ **Allogeneic, unrelated donor**

370. Same donor as current transplant? 1 ☐ Yes 0 ☐ No

	Yes	No			Yes	No	
371.	1 ☐	0 ☐	Bone marrow	**374.**	1 ☐	0 ☐	Fetal tissue
372.	1 ☐	0 ☐	Peripheral blood	**375.**	1 ☐	0 ☐	Other, specify: _____
373.	1 ☐	0 ☐	Cord blood				

376. Was this transplant reported to the IBMTR?
1 ☐ Yes — IBMTR I.D. ☐☐☐☐☐☐
0 ☐ No
8 ☐ Unknown

3 ☐ **Allogeneic, related donor**

377. Same donor as current transplant? 1 ☐ Yes 0 ☐ No

	Yes	No			Yes	No	
378.	1 ☐	0 ☐	Bone marrow	**380.**	1 ☐	0 ☐	Cord blood
379.	1 ☐	0 ☐	Peripheral blood	**381.**	1 ☐	0 ☐	Other, specify: _____

382. Was this transplant reported to the IBMTR?
1 ☐ Yes — IBMTR I.D. ☐☐☐☐☐☐
0 ☐ No
8 ☐ Unknown

383. Reason for re-transplant:
1 ☐ No engraftment
2 ☐ Partial engraftment
3 ☐ Graft failure/rejection
4 ☐ Persistent malignancy
5 ☐ Recurrent malignancy
6 ☐ Planned second transplant, per protocol
7 ☐ Other, specify: _____

384. What type of graft did patient receive for the current transplant?

1 ☐ Autologous — **385.** From where were stem cells obtained?
- 1 ☐ Bone marrow — *Complete INSERT* **AUTOBM**
- 2 ☐ Blood — *Complete INSERT* **AUTOPB**
- 3 ☐ Bone marrow & Blood — *Complete INSERTS* **AUTOBM & AUTOPB**

2 ☐ Allogeneic
3 ☐ Syngeneic
→ *Complete INSERT* **ALLOBM**

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Posttransplant Information

*Provide information for first 100 days after transplant **OR** until start of conditioning (high-dose therapy) for second or subsequent transplant if started < 100 days after initial transplant **OR** until infusion of cells for second transplant without conditioning if done < 100 days after initial transplant **OR** until donor leukocyte infusion done to treat relapse, infection, or lymphoproliferative disorder or graft failure if done < 100 days after initial transplant **OR** until time of death if death occurred < 100 days after transplant. If this form is being completed more than 100 days after transplant, provide data to 100 days on this form. Provide data for course after 100 days on a follow-up form.* ***IF YOU HAVE ANY QUESTIONS ABOUT HOW TO COMPLETE THIS SECTION OF THE FORM, PLEASE CONTACT THE STATISTICAL CENTER.***

386. Date of last actual contact with patient to determine medical status for this report: [ ][ ] Month [ ][ ] Day [ ][ ] Year

387. Did patient die prior to day 100 after this transplant?

1 ☐ Yes – *Answers to subsequent questions should reflect clinical status immediately prior to death*

0 ☐ No – *Answers to subsequent questions should reflect clinical status on day of actual contact for this follow-up examination (approximately 100 days posttransplant)*

388. Did patient receive a subsequent blood or marrow infusion after the transplant for which this report is being completed? **(other than peripheral blood leukocytes or T-lymphocytes from original allogeneic donor)**

1 ☐ Yes
0 ☐ No

Answers to the following questions should reflect clinical status immediately prior to start of conditioning for subsequent infusion. ***A separate report covering the subsequent transplant must be submitted.***

389. Date of subsequent infusion: [ ][ ] Month [ ][ ] Day [ ][ ] Year

390. Reason for subsequent infusion:

1 ☐ No engraftment
2 ☐ Partial engraftment
3 ☐ Late graft failure
4 ☐ Persistent malignancy
5 ☐ Relapse
6 ☐ Planned second transplant, per protocol
7 ☐ Other, specify: _____

391. Type of graft:

1 ☐ Allogeneic, related
2 ☐ Allogeneic, unrelated
3 ☐ Autologous

Donor:
1 ☐ Same donor
2 ☐ Different donor
3 ☐ Not applicable, initial transplant was autologous

Source of cells:

392. 1 ☐ Fresh
2 ☐ Cryopreserved

393. Check all that apply:

1 ☐ Yes 0 ☐ No Bone marrow
1 ☐ Yes 0 ☐ No Peripheral blood
1 ☐ Yes 0 ☐ No Cord blood
1 ☐ Yes 0 ☐ No Fetal tissue
1 ☐ Yes 0 ☐ No Other, specify: _____

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395. ***Allografts only:*** Has patient received an infusion of peripheral blood leukocytes or T-lymphocytes from the original donor?

1 ❑ Yes
0 ❑ No

396. Date first infusion given: ☐☐ ☐☐ ☐☐ (Month Day Year)

397. Patient weight within 2 weeks of first infusion: ☐☐ kg

398. Total number of infusions: ☐☐

399. Total dose of mononuclear cells given: ☐☐☐.☐ x 10^{10}

400. Were cells manipulated prior to infusion?

1 ❑ Yes
0 ❑ No

401. Indicate method:

1 ❑ T-cell depletion
2 ❑ CD34 selection
7 ❑ Other, specify: _____

402. Indication for the infusion(s) of donor cells:

1 ❑ Prophylaxis against B-cell lymphoproliferative disorder (or viral infection)
2 ❑ Prophylaxis against relapse
3 ❑ Treatment of relapse
4 ❑ Treatment of B-cell lymphoproliferative disorder
5 ❑ Treatment of viral infection, specify: _____
6 ❑ Graft failure
7 ❑ Other, specify: _____

If answers 3 – 7 were selected, then answers to following questions should reflect clinical status immediately prior to infusion. ***This is considered a transplant and a separate report covering this infusion and post-infusion events must be submitted.***

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Hematopoietic Reconstitution Posttransplant

403. Has patient received hematopoietic growth factors or cytokines posttransplant? 1 ☐ Yes 0 ☐ No

Specify agents given as planned therapy to promote engraftment:

Per Protocol:		Yes	No		Date Started Month	Day	Year		Date Stopped Month	Day	Year
G-CSF	**404.**	1 ☐	0 ☐	**405.**	☐☐	☐☐	☐☐	**406.**	☐☐	☐☐	☐☐
GM-CSF	**407.**	1 ☐	0 ☐	**408.**	☐☐	☐☐	☐☐	**409.**	☐☐	☐☐	☐☐
Interleukin-3	**410.**	1 ☐	0 ☐	**411.**	☐☐	☐☐	☐☐	**412.**	☐☐	☐☐	☐☐
Interleukin-6	**413.**	1 ☐	0 ☐	**414.**	☐☐	☐☐	☐☐	**415.**	☐☐	☐☐	☐☐
PIXY-321	**416.**	1 ☐	0 ☐	**417.**	☐☐	☐☐	☐☐	**418.**	☐☐	☐☐	☐☐
Stem Cell Factor (SCF)	**419.**	1 ☐	0 ☐	**420.**	☐☐	☐☐	☐☐	**421.**	☐☐	☐☐	☐☐
Blinded growth factor trial, specify agent(s) being studied:	**422.**	1 ☐	0 ☐	**423.**	☐☐	☐☐	☐☐	**424.**	☐☐	☐☐	☐☐
Other, specify:	**425.**	1 ☐	0 ☐	**426.**	☐☐	☐☐	☐☐	**427.**	☐☐	☐☐	☐☐

Coding for Indication of Therapy (below)
1. Intervention for delay/decline in Absolute Neutrophil Count (ANC)
2. Intervention for delay/decline in platelets
3. Intervention for delay/decline in both ANC and platelets
4. Intervention for delay/decline in red blood cell counts
5. Anti-leukemic or tumor agent to prevent relapse
6. Anti-leukemic or tumor agent to treat relapse
7. Other indication

Specify additional agents given:

		Yes	No		Date Started Month	Day	Year		Date Stopped Month	Day	Year		Indication
G-CSF	**428.**	1 ☐	0 ☐	**429.**	☐☐	☐☐	☐☐	**430.**	☐☐	☐☐	☐☐	**431.**	☐
GM-CSF	**432.**	1 ☐	0 ☐	**433.**	☐☐	☐☐	☐☐	**434.**	☐☐	☐☐	☐☐	**435.**	☐
Erythropoietin	**436.**	1 ☐	0 ☐	**437.**	☐☐	☐☐	☐☐	**438.**	☐☐	☐☐	☐☐	**439.**	☐
Thrombopoietin	**440.**	1 ☐	0 ☐	**441.**	☐☐	☐☐	☐☐	**442.**	☐☐	☐☐	☐☐	**443.**	☐
Interleukin-2	**444.**	1 ☐	0 ☐	**445.**	☐☐	☐☐	☐☐	**446.**	☐☐	☐☐	☐☐	**447.**	☐
Interleukin-3	**448.**	1 ☐	0 ☐	**449.**	☐☐	☐☐	☐☐	**450.**	☐☐	☐☐	☐☐	**451.**	☐
Interleukin-6	**452.**	1 ☐	0 ☐	**453.**	☐☐	☐☐	☐☐	**454.**	☐☐	☐☐	☐☐	**455.**	☐
PIXY-321	**456.**	1 ☐	0 ☐	**457.**	☐☐	☐☐	☐☐	**458.**	☐☐	☐☐	☐☐	**459.**	☐
Stem Cell Factor (SCF)	**460.**	1 ☐	0 ☐	**461.**	☐☐	☐☐	☐☐	**462.**	☐☐	☐☐	☐☐	**463.**	☐
Interferon-alpha	**464.**	1 ☐	0 ☐	**465.**	☐☐	☐☐	☐☐	**466**	☐☐	☐☐	☐☐	**467.**	☐
Interferon-gamma	**468.**	1 ☐	0 ☐	**469.**	☐☐	☐☐	☐☐	**470.**	☐☐	☐☐	☐☐	**471.**	☐
Blinded growth factor trial, specify agent(s) being studied:	**472.**	1 ☐	0 ☐	**473.**	☐☐	☐☐	☐☐	**474.**	☐☐	☐☐	☐☐	**475.**	☐
Other, specify:	**476.**	1 ☐	0 ☐	**477.**	☐☐	☐☐	☐☐	**478.**	☐☐	☐☐	☐☐	**479.**	☐

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480. Did patient receive other courses of growth factors or cytokines posttransplant?

1 ☐ Yes — *Photocopy Q.428–479 and answer for each additional course given.*
0 ☐ No
8 ☐ Unknown

Granulopoiesis

481. Is (was) there evidence of hematopoietic recovery following the initial bone marrow infusion? *(check only one)*

1 ☐ Yes, ANC ≥ 500/mm³ achieved and sustained for 3 consecutive days

482. Date ANC ≥ 500/mm³: *(First of 3 consecutive days)* ☐☐ Month ☐☐ Day ☐☐ Year

483. Was ANC ≥ 1000/mm³ achieved and sustained for 3 consecutive days?

1 ☐ Yes — **484.** Date achieved: ☐☐ Month ☐☐ Day ☐☐ Year ☐ Date unknown *(first of 3 consecutive days)*
0 ☐ No
8 ☐ Unknown

Go to Q. 512

2 ☐ Yes, ANC ≥ 500/mm³ for 3 consecutive days with subsequent decline in ANC to <500/mm³ for greater than 3 days

485. Date ANC ≥ 500/mm³: *(First of 3 consecutive days)* ☐☐ Month ☐☐ Day ☐☐ Year

486. Was ANC ≥ 1000/mm³ achieved and sustained for 3 consecutive days?

1 ☐ Yes — **487.** Date achieved: ☐☐ Month ☐☐ Day ☐☐ Year ☐ Date unknown *(first of 3 consecutive days)*
0 ☐ No
8 ☐ Unknown

488. Date of decline in ANC to < 500/mm³ for greater than 3 days: *(First of 3 days that ANC declined)* ☐☐ Month ☐☐ Day ☐☐ Year

489. Did patient recover and maintain ANC ≥ 500/mm³ following the decline?

1 ☐ Yes — **490.** Date of ANC recovery: ☐☐ Month ☐☐ Day ☐☐ Year
0 ☐ No

Go to Q. 491

3 ☐ No, ANC ≥ 500/mm³ was not achieved and there was no evidence of recurrent disease in the bone marrow — Go to Q. 491

4 ☐ No, ANC ≥ 500/mm³ was not achieved and there was documented persistent disease in the bone marrow posttransplant — Go to Q. 491

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Suspected etiology of failure to achieve ANC $\geq$ 500/mm^3 or of a decline in ANC:

491. Persistent disease or relapse:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

492. Graft versus host disease:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

493. Immune-mediated rejection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

494. Non-viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

495. Suspected viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus suspected:

	Yes	No	
496.	1 ❑	0 ❑	Cytomegalovirus (CMV)
497.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
498.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
499.	1 ❑	0 ❑	Varicella
500.	1 ❑	0 ❑	Other, specify: _____

501. Documented viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus involved:

	Yes	No	
502.	1 ❑	0 ❑	Cytomegalovirus (CMV)
503.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
504.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
505.	1 ❑	0 ❑	Varicella
506.	1 ❑	0 ❑	Other, specify: _____

507. Drugs:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

	Yes	No	
508.	1 ❑	0 ❑	Ganciclovir
509.	1 ❑	0 ❑	Bactrim, Septra, Trimethoprim-sulfamethoxazole
510.	1 ❑	0 ❑	Other, specify: _____

511. Etiology undetermined:
- 1 ❑ Yes
- 0 ❑ No

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Megakaryopoiesis

The following questions relate to initial platelet recovery. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory results.

512. Was a platelet count of ≥ 20 x 10^9/L achieved?

1 ❑ Yes → **513.** Date platelets ≥ 20 x 10^9/L: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No → Go to Q. 518

8 ❑ Unknown → Go to Q. 518

514. Was a platelet count of ≥ 50 x 10^9/L achieved?

1 ❑ Yes → **515.** Date platelets ≥ 50 x 10^9/L: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No → Go to Q. 518

8 ❑ Unknown → Go to Q. 518

516. Was a platelet count of ≥ 100 x 10^9/L achieved?

1 ❑ Yes → **517.** Date platelets ≥ 100 x 10^9/L: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No

8 ❑ Unknown

518. Was patient ever platelet transfusion independent?

1 ❑ Yes → **519.** Date of last (most recent) platelet transfusion*: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No

8 ❑ Unknown

7 ❑ Not applicable (never dependent)

**If patient was platelet transfusion independent for ≥14 days but subsequently experienced a decline in platelet count and required platelet transfusions, record date of last platelet transfusion before decline in counts. If patient has not required platelet transfusions since initial date of recovery, record date of last platelet transfusion.*

520. Is patient now receiving platelet transfusions?

1 ❑ Yes

0 ❑ No

8 ❑ Unknown

Erythropoiesis

521. Has patient received red blood cell (RBC) transfusions within 20 days of the day of last contact?

1 ❑ Yes → **522.** Date of last (most recent) RBC transfusion*: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No

**If patient was RBC transfusion independent for ≥1 month but subsequently experienced a decline in RBC count and required RBC transfusions, record date of last RBC transfusion before decline in counts. If patient has not required RBC transfusions since initial date of recovery, record date of last RBC transfusion.*

523. Is patient now receiving RBC transfusions?

1 ❑ Yes

0 ❑ No

8 ❑ Unknown

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Current Hematologic Findings

Date of most recent CBC: ☐☐ Month ☐☐ Day ☐☐ Year

Actual CBC results:

WBC: ☐☐☐.☐ x 10^9/L

Neutrophils: ☐☐ %

Lymphocytes: ☐☐ %

Hemoglobin: ☐☐☐☐.☐☐ ☐ Transfused

Hematocrit: ☐☐ % ☐ Transfused

Platelets: ☐☐ x 10^9/L ☐ Transfused

Specify units for hemoglobin: ☐ g/dL ☐ g/L ☐ mmol/L

Acute Graft-vs-Host Disease (GVHD)

524. Was specific therapy used posttransplant to prevent or induce acute GVHD, or promote engraftment?

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

Allografts: Go to Q. 541

Autografts: Go to Q. 680

For each agent listed below indicate whether or not it was used to prevent or induce acute GVHD:

	Yes	No	
525.	1 ☐	0 ☐	Methotrexate
526.	1 ☐	0 ☐	Cyclosporine
527.	1 ☐	0 ☐	FK 506 (Tacrolimus)
528.	1 ☐	0 ☐	Corticosteroids
529.	1 ☐	0 ☐	ALS, ALG, ATS, ATG
530.	1 ☐	0 ☐	Azathioprine
531.	1 ☐	0 ☐	Cyclophosphamide
532.	1 ☐	0 ☐	In vivo anti T-lymphocyte monoclonal antibody
538.	1 ☐	0 ☐	In vivo immunotoxin, specify: _____
539.	1 ☐	0 ☐	Blinded randomized trial; specify agent being studied: _____
540.	1 ☐	0 ☐	Other, specify: _____

	Yes	No	
533.	1 ☐	0 ☐	Anti IL-2
534.	1 ☐	0 ☐	Anti CD 25
535.	1 ☐	0 ☐	Campath
536.	1 ☐	0 ☐	OKT3
537.	1 ☐	0 ☐	Other, specify: _____

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541. Did acute GVHD occur?

1 ☐ Yes
0 ☐ No — Go to Q. 593
8 ☐ Unknown — Go to Q. 593

542. Maximum overall grade: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV

What was diagnosis based on?

543. Histologic evidence:
1 ☐ Yes
0 ☐ No

548. Clinical evidence:
1 ☐ Yes
0 ☐ No

Sites:

	Yes	No	
544.	1 ☐	0 ☐	Skin
545.	1 ☐	0 ☐	Gut
546.	1 ☐	0 ☐	Liver
547.	1 ☐	0 ☐	Other, specify: _____

549. Date of onset: ☐☐ ☐☐ ☐☐ (Month Day Year)

550. Was acute GVHD still present at time of this report?
1 ☐ Yes
0 ☐ No
2 ☐ Progressed to chronic GVHD
8 ☐ Unknown

List the maximum severity of organ involvement attributed to acute GVHD:

	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
551. Skin:	1 ☐ No rash	2 ☐ Maculopapular rash, <25% of body surface	3 ☐ Maculopapular rash, 25–50% of body surface	4 ☐ Generalized erythroderma	5 ☐ Generalized erythroderma with bullae formation and desquamation
552. Intestinal tract (use ml/day for adult patients and ml/m²/day for pediatric patients):	0 ☐ No diarrhea 1 ☐ Diarrhea ≤500 ml/day or <280 ml/m²/day	2 ☐ Diarrhea >500 but ≤1000 ml/day or 280–555 ml/m²/day	3 ☐ Diarrhea >1000 but ≤1500 ml/day or 556–833 ml/m²/day	4 ☐ Diarrhea >1500 ml/day or >833 ml/m²/day	5 ☐ Severe abdominal pain, with or without ileus
553. Liver:	1 ☐ Bilirubin <2.0 mg/dL	2 ☐ Bilirubin 2.0–3.0 mg/dL	3 ☐ Bilirubin 3.1–6.0 mg/dL	4 ☐ Bilirubin 6.1–15.0 mg/dL	5 ☐ Bilirubin >15.0 mg/dL

554. Other organ involvement?
1 ☐ Yes
0 ☐ No

	Yes	No	
555.	1 ☐	0 ☐	Upper GI tract
556.	1 ☐	0 ☐	Lung
557.	1 ☐	0 ☐	Other, specify: _____

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558. Was specific therapy used to **treat** acute GVHD? 1 ☐ Yes 0 ☐ No — Go to Q. 593

For each agent listed below indicate whether or not it was used to **treat** acute GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking? Yes	Still taking? No
559. Methotrexate	0 ☐	1 ☐	2 ☐	3 ☐	**560.** 1 ☐	0 ☐
561. Cyclosporine	0 ☐	1 ☐	2 ☐	3 ☐	**562.** 1 ☐	0 ☐
563. FK 506 (Tacrolimus)	0 ☐	1 ☐	2 ☐	3 ☐	**564.** 1 ☐	0 ☐
565. Systemic Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**566.** 1 ☐	0 ☐
567. Topical Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**568.** 1 ☐	0 ☐
569. ALS, ALG, ATS, ATG	0 ☐	1 ☐	2 ☐	3 ☐	**570.** 1 ☐	0 ☐
571. Azathioprine	0 ☐	1 ☐	2 ☐	3 ☐	**572.** 1 ☐	0 ☐
573. Cyclo-phosphamide	0 ☐	1 ☐	2 ☐	3 ☐	**574.** 1 ☐	0 ☐
575. Thalidomide	0 ☐	1 ☐	2 ☐	3 ☐	**576.** 1 ☐	0 ☐
In vivo anti-T-lymphocyte monoclonal antibody:						
577. Anti IL-2	0 ☐	1 ☐	2 ☐	3 ☐	**578.** 1 ☐	0 ☐
579. Anti CD 25	0 ☐	1 ☐	2 ☐	3 ☐	**580.** 1 ☐	0 ☐
581. Campath	0 ☐	1 ☐	2 ☐	3 ☐	**582.** 1 ☐	0 ☐
583. OKT3	0 ☐	1 ☐	2 ☐	3 ☐	**584.** 1 ☐	0 ☐
585. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**586.** 1 ☐	0 ☐
587. In vivo immunotoxin, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**588.** 1 ☐	0 ☐
589. Blinded randomized trial; specify agent being studied: _____	0 ☐	1 ☐	2 ☐	3 ☐	**590.** 1 ☐	0 ☐
591. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**592.** 1 ☐	0 ☐

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Chronic Graft-vs-Host Disease (GVHD)

593. Has patient developed clinical chronic GVHD?

1 ❑ Yes
0 ❑ No — Go to Q. 680
8 ❑ Unknown — Go to Q. 680

594. Date of onset: ☐☐ Month ☐☐ Day ☐☐ Year

595. Progressed from acute GVHD?
1 ❑ Yes
0 ❑ No

596. Karnofsky/Lansky score (see page 5) at diagnosis of chronic GVHD: ☐☐☐

597. Platelet count at diagnosis of chronic GVHD: ☐☐☐☐.☐ x 10^9/L

598. Total serum bilirubin at diagnosis of chronic GVHD: ☐☐.☐

599. Unit of measurement for bilirubin:
1 ❑ mg/dL
2 ❑ μmol/L

What was diagnosis based on?

600. Histologic evidence:
1 ❑ Yes
0 ❑ No

609. Clinical evidence:
1 ❑ Yes
0 ❑ No

Sites:

	Yes	No	
601.	1 ❑	0 ❑	Skin
602.	1 ❑	0 ❑	Gut
603.	1 ❑	0 ❑	Liver
604.	1 ❑	0 ❑	Buccal mucosa/lip
605.	1 ❑	0 ❑	Conjunctiva
606.	1 ❑	0 ❑	Lung
607.	1 ❑	0 ❑	Muscle
608.	1 ❑	0 ❑	Other, specify: _____

610. Maximum grade of chronic GVHD:

1 ❑ Limited (*Localized skin involvement and/or hepatic dysfunction due to chronic GVHD*)

2 ❑ Extensive *(Generalized skin involvement; or localized skin involvement and/or hepatic dysfunction due to chronic GVHD, plus :*
-Liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
-Involvement of eye: Schirmer's test with < 5 mm wetting; or,
-Involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or,
-Involvement of any other target organ)

611. Overall severity: 1 ❑ Mild 2 ❑ Moderate 3 ❑ Severe

Continued on next page

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Indicate organ involvement with chronic GVHD from list below:

		Yes	No	
Skin/Hair:	**612.**	1 ❑	0 ❑	Subclinical (biopsy findings only)
	613.	1 ❑	0 ❑	Rash
	614.	1 ❑	0 ❑	Scleroderma
	615.	1 ❑	0 ❑	Dyspigmentation
	616.	1 ❑	0 ❑	Contractures
	617.	1 ❑	0 ❑	Alopecia
	618.	1 ❑	0 ❑	Other skin/hair involvement, specify: _____
Eyes:	**619.**	1 ❑	0 ❑	Dry eyes
	620.	1 ❑	0 ❑	Corneal erosion/conjunctivitis
	621.	1 ❑	0 ❑	Other eye involvement, specify: _____
Mouth:	**622.**	1 ❑	0 ❑	Lichenoid changes
	623.	1 ❑	0 ❑	Mucositis/ulcers
	624.	1 ❑	0 ❑	Other mouth involvement, specify: _____
Lung:	**625.**	1 ❑	0 ❑	Bronchiolitis obliterans
	626.	1 ❑	0 ❑	Other lung involvement, specify: _____
GI Tract:	**627.**	1 ❑	0 ❑	Esophageal involvement
	628.	1 ❑	0 ❑	Chronic nausea/vomiting
	629.	1 ❑	0 ❑	Chronic diarrhea
	630.	1 ❑	0 ❑	Malabsorption
	631.	1 ❑	0 ❑	Other GI tract involvement, specify: _____
Liver:	**632.**	1 ❑	0 ❑	Liver involvement, specify: _____
GU Tract:	**633.**	1 ❑	0 ❑	Vaginitis/stricture
	634.	1 ❑	0 ❑	Other GU involvement, specify: _____
Musculoskeletal:	**635.**	1 ❑	0 ❑	Arthritis
	636.	1 ❑	0 ❑	Myositis
	637.	1 ❑	0 ❑	Myasthenia
	638.	1 ❑	0 ❑	Other musculoskeletal involvement, specify: _____
Hematologic:	**639.**	1 ❑	0 ❑	Thrombocytopenia
	640.	1 ❑	0 ❑	Eosinophilia
	641.	1 ❑	0 ❑	Autoantibodies
	642.	1 ❑	0 ❑	Other hematologic involvement, specify: _____
Other:	**643.**	1 ❑	0 ❑	Specify: _____

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644. Was specific therapy used to **treat** chronic GVHD? 1 ☐ Yes 0 ☐ No — Go to Q. 679

For each agent listed below indicate whether or not it was used to **treat** chronic GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking? Yes	Still taking? No
645. ALS, ALG, ATS, ATG	0 ☐	1 ☐	2 ☐	3 ☐	**646.** 1 ☐	0 ☐
647. Azathioprine	0 ☐	1 ☐	2 ☐	3 ☐	**648.** 1 ☐	0 ☐
649. Cyclosporine	0 ☐	1 ☐	2 ☐	3 ☐	**650.** 1 ☐	0 ☐
651. FK 506 (Tacrolimus)	0 ☐	1 ☐	2 ☐	3 ☐	**652.** 1 ☐	0 ☐
653. Systemic Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**654.** 1 ☐	0 ☐
655. Topical Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**656.** 1 ☐	0 ☐
657. Cyclo-phosphamide	0 ☐	1 ☐	2 ☐	3 ☐	**658.** 1 ☐	0 ☐
659. Thalidomide	0 ☐	1 ☐	2 ☐	3 ☐	**660.** 1 ☐	0 ☐
In vivo anti-T-lymphocyte monoclonal antibody						
661. Anti IL-2	0 ☐	1 ☐	2 ☐	3 ☐	**662.** 1 ☐	0 ☐
663. Anti CD 25	0 ☐	1 ☐	2 ☐	3 ☐	**664.** 1 ☐	0 ☐
665. Campath	0 ☐	1 ☐	2 ☐	3 ☐	**666.** 1 ☐	0 ☐
667. OKT3	0 ☐	1 ☐	2 ☐	3 ☐	**668.** 1 ☐	0 ☐
669. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**670.** 1 ☐	0 ☐
671. In vivo immunotoxin, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**672.** 1 ☐	0 ☐
673. Blinded randomized trial; specify agent being studied: _____	0 ☐	1 ☐	2 ☐	3 ☐	**674.** 1 ☐	0 ☐
675. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**676.** 1 ☐	0 ☐

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677. Is patient still receiving treatment for chronic GVHD?

1 ☐ Yes
0 ☐ No

678. Date last treatment was administered: ☐☐ ☐☐ ☐☐
Month Day Year

679. Is chronic GVHD still present?

1 ☐ Yes
0 ☐ No
2 ☐ No symptoms, but patient still receiving treatment

Other Treatment and Clinical Status After Start of Conditioning

680. Were transfusions given at any time after the start of conditioning to present?

1 ☐ Yes
0 ☐ No

	Yes	No	
681.	1 ☐	0 ☐	Did patient receive only CMV-negative blood products?
682.	1 ☐	0 ☐	Were blood products filtered to remove leukocytes?
683.	1 ☐	0 ☐	Were all transfusions irradiated?

684. Number of RBC transfusions in first 60 days: ☐☐☐ units

685. Number of platelet transfusions in first 60 days: ☐☐☐ units

686. Did patient receive any of the following agents for infection prophylaxis after start of conditioning?

1 ☐ Yes
0 ☐ No

	Yes	No	
	1 ☐	0 ☐	Systemic antibacterial antibiotics
	1 ☐	0 ☐	Nonabsorbable antibiotics
687.	1 ☐	0 ☐	Polyclonal IV gamma globulin (not ATG)
688.	1 ☐	0 ☐	CMV/hyperimmune gamma globulin
689.	1 ☐	0 ☐	IV amphotericin
690.	1 ☐	0 ☐	Fluconazole
691.	1 ☐	0 ☐	Itraconazole
692.	1 ☐	0 ☐	Other systemic antifungal agent, specify:_____
693.	1 ☐	0 ☐	Acyclovir
694.	1 ☐	0 ☐	Ganciclovir (DHPG)
695.	1 ☐	0 ☐	Foscarnet
696.	1 ☐	0 ☐	Other antiviral agent, specify: _____
697.	1 ☐	0 ☐	Trimethoprim-sulfamethoxazole (Bactrim/Septra)
698.	1 ☐	0 ☐	Pentamidine inhaled
699.	1 ☐	0 ☐	Pentamidine IV
700.	1 ☐	0 ☐	Dapsone
701.	1 ☐	0 ☐	Other pneumocystis prophylaxis, specify:_____
702.	1 ☐	0 ☐	Other, specify:_____

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703. Did patient develop clinically significant infection after start of conditioning? 1 ❑ Yes 0 ❑ No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism was involved, list one site of infection and organism on the first line; second site and/or organism on second line.

			Site	Organism	Date of Onset Month	Day	Year	Did infection resolve? Yes	No
704. ❑ Bacterial									
Typical	First	**705.**		**706.** _____	**707.**			**708.** 1 ❑	0 ❑
	Second	**709.**		**710.** _____	**711.**			**712.** 1 ❑	0 ❑
Atypical	First	**716.**		**717.** B	**718.**			**719.** 1 ❑	0 ❑
	Second	**720.**		**721.** B	**722.**			**723.** 1 ❑	0 ❑

724. Other atypical bacterium, specify: _____

727. ❑ Fungal									
	First	**728.**		**729.** F	**730.**			**731.** 1 ❑	0 ❑
	Second	**732.**		**733.** F	**734.**			**735.** 1 ❑	0 ❑

736. Other fungus, specify: _____

739. ❑ Viral									
	First	**740.**		**741.** V	**742.**			**743.** 1 ❑	0 ❑
	Second	**744.**		**745.** V	**746.**			**747.** 1 ❑	0 ❑

748. Other virus, specify: _____

751. ❑ Parasitic									
	First	**752.**		**753.** P	**754.**			**755.** 1 ❑	0 ❑
	Second	**756.**		**757.** P	**758.**			**759.** 1 ❑	0 ❑

760. Other parasite, specify: _____

763. ❑ No organism identified									
	First	**764.**		**765.** O509	**766.**			**767.** 1 ❑	0 ❑
	Second	**768.**		**769.** O509	**770.**			**771.** 1 ❑	0 ❑

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Codes for Common Sites of Infection

01 Blood / buffy coat
02 Disseminated – generalized, isolated at 3 or more distinct sites
03 *Central Nervous System unspecified*
04 Brain
05 Spinal cord
06 Meninges and CSF
10 *Gastrointestinal Tract unspecified*
11 Lips
12 Tongue, oral cavity and oro-pharynx
13 Esophagus
14 Stomach
15 Gallbladder and biliary tree (not hepatitis), pancreas
16 Small intestine
17 Large intestine
18 Feces/stool
19 Peritoneum
20 Liver
30 *Respiratory unspecified*
31 Upper airway and nasopharynx
32 Laryngitis/larynx
33 Lower respiratory tract (lung)
34 Pleural cavity, pleural fluid
35 Sinuses
40 *Genito-Urinary Tract unspecified*
41 Kidneys, renal pelvis, ureters and bladder
42 Prostate
43 Testes
44 Fallopian tubes, uterus, cervix
45 Vagina
50 *Skin unspecified*
51 Genital area
52 Cellulitis
53 Herpes Zoster
54 Rash, pustules or abscesses not typical of any of the above
60 Central venous catheter, not otherwise specified
61 Catheter insertion site
62 Catheter tip
70 Eyes
75 Ear
80 *Other unspecified*
81 Joints
82 Bone marrow
83 Bone cortex (osteomyelitis)
84 Muscle (excluding cardiac)
85 Cardiac (endocardium, myocardium, pericardium)
86 Lymph nodes
87 Spleen

Codes for Commonly Reported Organisms

1. Bacteria

(Indicate code for atypical bacteria; list bacterium for non-atypical bacteria.)

100 Atypical bacteria, not otherwise specified
101 Coxiella
102 Legionella
103 Leptospira
104 Listeria
105 Mycoplasma
106 Nocardia
107 Rickettsia
110 Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
111 Typical tuberculosis (TB, Tuberculosis)
112 Mycobacteria (avium, bovium, intracellulare)
113 Chlamydia
119 Other atypical bacteria, specify

2. Fungal Infections

200 Candida, not otherwise specified
201 Candida albicans
202 Candida krusei
203 Candida parapsilosis
204 Candida tropicalis
205 Torulopsis glabrata (a subspecies of candida)
209 Candida, other
210 Aspergillus, not otherwise specified
211 Aspergillus flavus
212 Aspergillus fumigatus
213 Aspergillus niger
219 Aspergillus, other
220 Cryptococcus species
230 Fusarium species
240 Mucormycosis (zygomycetes, rhizopus)
250 Yeast, not otherwise specified
259 Other fungus, specify

3. Viral Infections

301 Herpes Simplex (HSV1, HSV2)
302 Herpes Zoster (Chicken pox, Varicella)
303 Cytomegalovirus (CMV)
304 Adenovirus
305 Enterovirus (Coxsackie, Echo, Polio)
306 Hepatitis A (HAV)
307 Hepatitis B (HBV, Australian antigen)
308 Hepatitis C (HCV)
309 HIV-1 (HTLV-III)
310 Influenza
311 Measles (Rubeola)
312 Mumps
313 Papovavirus
314 Respiratory syncytial virus (RSV)
315 Rubella (German Measles)
316 Parainfluenza
317 Human herpesvirus-6 (HHV-6)
318 Epstein-Barr virus (EBV)
319 Polyomavirus
320 Rotavirus
321 Rhinovirus
329 Other viral, specify

4. Parasite Infections

401 Pneumocystis (PCP)
402 Toxoplasma
403 Giardia
404 Cryptosporidium
409 Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

5. Other Infections

509 No organism identified

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Pulmonary function

775. Has patient developed interstitial pneumonitis (IPn)?

Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload.

1 ☐ Yes
0 ☐ No

776. How many episodes of IPn occurred? ☐

Note: If more than one episode of IPn, photocopy this page and complete Q. 775 – 795 for subsequent episode(s).

777. Date of onset of IPn: ☐☐ ☐☐ ☐☐
Month Day Year

778. Were diagnostic tests other than radiographic studies done?

1 ☐ Yes
0 ☐ No

Diagnosis was evaluated by:

	Yes	No	
779.	1 ☐	0 ☐	Bronchoalveolar lavage
780.	1 ☐	0 ☐	Transbronchial biopsy
781.	1 ☐	0 ☐	Open lung biopsy
782.	1 ☐	0 ☐	Autopsy
783.	1 ☐	0 ☐	Other, specify: _____

784. Was an organism isolated?

1 ☐ Yes
0 ☐ No (idiopathic, or no organism isolated)

Etiology:

	Yes	No	
785.	1 ☐	0 ☐	Pneumocystis carinii
786.	1 ☐	0 ☐	Aspergillus
787.	1 ☐	0 ☐	Candida toxoplasma
788.	1 ☐	0 ☐	Respiratory syncytial virus
789.	1 ☐	0 ☐	Cytomegalovirus
790.	1 ☐	0 ☐	Herpes simplex
791.	1 ☐	0 ☐	Adenovirus
792.	1 ☐	0 ☐	Human herpes virus 6
793.	1 ☐	0 ☐	Other virus, specify: _____
794.	1 ☐	0 ☐	Other, specify: _____

795. Has interstitial pneumonitis resolved?

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

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796. Did patient develop pulmonary abnormalities other than interstitial pneumonitis after start of conditioning?

1 ❑ Yes
0 ❑ No

797. Did patient develop Acute Respiratory Distress Syndrome (ARDS)?

1 ❑ Yes
0 ❑ No

798. Date of onset of ARDS: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

799. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
800.	1 ❑	0 ❑	Bronchoalveolar lavage
801.	1 ❑	0 ❑	Transbronchial biopsy
802.	1 ❑	0 ❑	Open lung biopsy
803.	1 ❑	0 ❑	Autopsy
804.	1 ❑	0 ❑	Other, specify: _____

805. Did patient develop bronchiolitis obliterans?

1 ❑ Yes
0 ❑ No

806. Date of onset: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

807. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
808.	1 ❑	0 ❑	Bronchoalveolar lavage
809.	1 ❑	0 ❑	Transbronchial biopsy
810.	1 ❑	0 ❑	Open lung biopsy
811.	1 ❑	0 ❑	Autopsy
812.	1 ❑	0 ❑	Other, specify: _____

813. Did patient develop pulmonary hemorrhage?

1 ❑ Yes
0 ❑ No

814. Date of onset: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

815. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
816.	1 ❑	0 ❑	Bronchoalveolar lavage
817.	1 ❑	0 ❑	Transbronchial biopsy
818.	1 ❑	0 ❑	Open lung biopsy
819.	1 ❑	0 ❑	Autopsy
820.	1 ❑	0 ❑	Other, specify: _____

821. Did patient develop other non-infectious pulmonary abnormalities?

1 ❑ Yes
0 ❑ No

822. Specify: _____

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Liver function

823. Patient's maximum total bilirubin in the first 100 days posttransplant: ☐☐.☐

824. Unit of measurement for bilirubin: • 1 ❑ mg/dL 2 ❑ μmol/L

825. Date of maximum total bilirubin in the first 100 days posttransplant: ☐☐ Month ☐☐ Day ☐☐ Year

826. Patient's bilirubin on day of last contact: ☐☐.☐ *(Refer to Q. 386, page 17 for date)*

827. Unit of measurement for bilirubin: 1 ❑ mg/dL 2 ❑ μmol/L

828. Did patient develop any of the following clinical signs/symptoms of abnormal liver function?

1 ❑ Yes
0 ❑ No

	Yes	No	
829.	1 ❑	0 ❑	Jaundice
830.	1 ❑	0 ❑	Hepatomegaly
831.	1 ❑	0 ❑	Right upper quadrant pain
832.	1 ❑	0 ❑	Ascites
833.	1 ❑	0 ❑	Weight gain (>5%)
834.	1 ❑	0 ❑	Other, specify: _____

835. Did patient develop non-infectious liver toxicity after conditioning?

1 ❑ Yes
0 ❑ No

836. What was the date of onset? ☐☐ Month ☐☐ Day ☐☐ Year

Etiology:

	Yes	No	
837.	1 ❑	0 ❑	Veno-occlusive disease
838.	1 ❑	0 ❑	Other, specify: _____
839.	1 ❑	0 ❑	Unknown

Diagnosis was based on:

	Yes	No	
840.	1 ❑	0 ❑	Clinical signs and symptoms (*see Q. 828*)
841.	1 ❑	0 ❑	Elevated liver enzymes
842.	1 ❑	0 ❑	Biopsy
843.	1 ❑	0 ❑	Autopsy
844.	1 ❑	0 ❑	Ultrasonography
845.	1 ❑	0 ❑	Doppler
846.	1 ❑	0 ❑	Other, specify: _____

847. Has liver toxicity resolved?

1 ❑ Yes
0 ❑ No

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848. Did patient develop any other non-infectious clinically significant organ impairment or disorder after conditioning?

1 ❑ Yes
0 ❑ No

	Yes	No	
849.	1 ❑	0 ❑	Renal failure requiring dialysis
850.	1 ❑	0 ❑	TTP/HUS or similar syndrome
851.	1 ❑	0 ❑	Hemorrhage, specify site:
852.	1 ❑	0 ❑	CNS
853.	1 ❑	0 ❑	Upper GI tract
854.	1 ❑	0 ❑	Lower GI tract
855.	1 ❑	0 ❑	Other, specify: _____
856.	1 ❑	0 ❑	Hemorrhagic cystitis
857.	1 ❑	0 ❑	Seizures
858.	1 ❑	0 ❑	Cataracts
859.	1 ❑	0 ❑	Avascular necrosis
860.	1 ❑	0 ❑	Hypothyroidism
861.	1 ❑	0 ❑	Gonadal dysfunction
862.	1 ❑	0 ❑	Growth hormone deficiency/growth disturbance
863.	1 ❑	0 ❑	Other, specify: _____

864. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear? *(If more than one new malignancy developed, copy this page and complete for each new cancer)*

1 ❑ Yes
0 ❑ No

865. Date of diagnosis: ☐☐ Month ☐☐ Day ☐☐ Year

866. Origin of cells:
1 ❑ Host 8 ❑ Unknown
2 ❑ Donor 7 ❑ Not tested

Diagnosis (***send copy of pathology report/other documentation***):

	Yes	No	
867.	1 ❑	0 ❑	Clonal cytogenetic abnormality without leukemia or MDS
868.	1 ❑	0 ❑	Acute myeloid leukemia
869.	1 ❑	0 ❑	Other leukemia, specify: _____
870.	1 ❑	0 ❑	Myelodysplasia
871.	1 ❑	0 ❑	Lymphoma or lymphoproliferative disease

872. EBV positive? 1 ❑ Yes 0 ❑ No 8 ❑ Unknown

873.	1 ❑	0 ❑	Hodgkin disease
875.	1 ❑	0 ❑	Other cancer

876. Primary site: _____

877. Histologic type: _____

878. Behavior:
1 ❑ Benign
2 ❑ In situ
3 ❑ Malignant/invasive
8 ❑ Unknown

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

Survival and Functional Status

879. Was patient discharged from hospital after transplant?

1 ❑ Yes
0 ❑ No
7 ❑ Not applicable, high-dose therapy given as outpatient

880. Date of first discharge from hospital after transplant: ☐☐ Month ☐☐ Day ☐☐ Year

881. ***Autografts only:*** Total number inpatient days in first 60 days after start of high-dose therapy: ☐☐

882. ***Allografts only:*** Total number inpatient days in first 100 days after start of high-dose therapy: ☐☐☐

883. Was patient alive on the day of last contact? (*Refer to Q. 386, page 17 for date*):

1 ❑ Yes
0 ❑ No

Go to Q. 895

884. *If the patient is 16 years of age or older, complete the Karnofsky Scale. If the patient is younger than 16 years of age, complete the Lansky Scale.*

Karnofsky Scale (age ≥16 yrs)

Select the phrase in the Karnofsky Scale which best describes the activity status of the patient:

Able to carry on normal activity; no special care is needed.
- ❑ 100 Normal; no complaints; no evidence of disease
- ❑ 90 Able to carry on normal activity
- ❑ 80 Normal activity with effort

Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.
- ❑ 70 Cares for self; unable to carry on normal activity or to do active work
- ❑ 60 Requires occasional assistance but is able to care for most needs
- ❑ 50 Requires considerable assistance and frequent medical care

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.
- ❑ 40 Disabled; requires special care and assistance
- ❑ 30 Severely disabled; hospitalization indicated, although death not imminent
- ❑ 20 Very sick; hospitalization necessary
- ❑ 10 Moribund; fatal process progressing rapidly

Lansky Scale (age <16 yrs)

Select the phrase in the Lansky Play-Performance Scale which best describes the activity status of the patient:

Normal range.
- ❑ 100 Fully active
- ❑ 90 Minor restriction in physically strenuous play
- ❑ 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction.
- ❑ 70 Both greater restrictions of, and less time spent in, active play
- ❑ 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- ❑ 50 Considerable assistance required for any active play; fully able to engage in quiet play

Moderate to severe restriction.
- ❑ 40 Able to initiate quiet activities
- ❑ 30 Needs considerable assistance for quiet activity
- ❑ 20 Limited to very passive activity initiated by others (i.e., TV)
- ❑ 10 Completely disabled, not even passive play

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(If patient is alive, answer Q.885–894; if dead, skip to Q. 895)

885. Patient (age ≥ 6 years) currently attends school:

1 ❑ Yes
0 ❑ No

→ **886.** 1 ❑ Part-time 2 ❑ Full-time 8 ❑ Unknown, whether part-time or full-time

887. Date returned to school: ☐☐ ☐☐ Month Year

888. Patient was employed outside the home prior to current illness:

1 ❑ Yes
0 ❑ No

→ **889.** Patient has returned to work:

1 ❑ Yes
0 ❑ No

→ **890.** Date returned to work: ☐☐ ☐☐ Month Year

891. Patient able to work but is not employed:

1 ❑ Yes
0 ❑ No

→ **892.** Patient has resumed all household activities:

1 ❑ Yes
0 ❑ No

→ **893.** Date resumed all activities: ☐☐ ☐☐ Month Year

894. Patient is a student:

1 ❑ Yes
0 ❑ No

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

Death Information

895. Date of death: ☐☐ ☐☐ ☐☐
Month Day Year

Cause(s) of death:

Enter appropriate cause of death below. If a code number for "Other, specify" is entered, write the cause in the space provided.

896. Primary: ☐☐☐ Specify: _____

Contributing or secondary causes:

897. ☐☐☐ Specify: _____

898. ☐☐☐ Specify: _____

899. ☐☐☐ Specify: _____

900. ☐☐☐ Specify: _____

901. ☐☐☐ Specify: _____

Cause of Death Codes

10 Graft rejection or failure

Infection (other than interstitial pneumonia)
- 20 Infection, organism not identified
- 21 Bacterial
- 22 Fungal
- 23 Viral
- 24 Protozoal
- 29 Other infection, specify

Interstitial pneumonia
- 30 IPn, idiopathic
- 31 Cytomegalovirus (CMV)
- 32 Viral, other
- 33 Pneumocystis (PCP)
- 34 Fungal
- 39 Other IPn, specify

40 Adult Respiratory Distress Syndrome, ARDS (other than IPN)

50 Acute GVHD
60 Chronic GVHD

70 Recurrence or persistence of primary disease

NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.

Organ failure (not due to GVHD or infection)
- 80 Organ failure, not otherwise specified
- 81 Liver (not VOD)
- 82 VOD
- 83 Cardiac (Cardiomyopathy)
- 84 Pulmonary
- 85 CNS
- 86 Renal
- 89 Other organ failure, specify

90 Secondary malignancy

100 Hemorrhage

110 Accidental death

900 Other, specify

902. Was cause of death confirmed by autopsy?

1 ☐ Yes — ***Send copy of autopsy report when available***
0 ☐ No
8 ☐ Unknown
6 ☐ Pending

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

FOR REGISTRY USE ONLY:

I.D. [ ] – [ ][ ][ ][ ] – [ ][ ][ ][ ][ ][ ]

Date received:

Registry: IBMTR ABMTR (circle one)

Confidential/Socioeconomic Information

903. Patient's First Name: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

904. Patient's Last Name: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

905. Patient's state of residence (*US only*): [ ][ ]

906. Zip code for place of patient's residence (*US only*): [ ][ ][ ][ ][ ] – [ ][ ][ ][ ]

907. Country of residence (*if non-US*): [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

908. Does patient have a US Social Security Number or Canadian Social Insurance Number?

1 ☐ Yes — **909.** Social Security or Social Insurance Number: [ ][ ][ ][ ][ ][ ][ ][ ][ ]

0 ☐ No

8 ☐ Unknown

7 ☐ Not applicable

910. (*For patients ≥18 years of age*) What is patient's marital status? (*check one*)

1 ☐ Single, never married

2 ☐ Married

3 ☐ Separated

4 ☐ Divorced

5 ☐ Widowed

8 ☐ Unknown

911. (*For patients ≥18 years of age*) What is the highest grade patient finished in school?

1 ☐ 1 – 8 grades

2 ☐ 9 – 11 grades

3 ☐ High School graduate

4 ☐ Some college

5 ☐ Junior college degree

6 ☐ College degree (BA/BS)

7 ☐ Some post-college work

8 ☐ Advanced degree

88 ☐ Unknown

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

912. What type of health insurance does patient have? (*check all that apply*)

0 ❑ No Insurance
1 ❑ Medicaid
2 ❑ Medicare (US)
3 ❑ Disability Insurance
4 ❑ HMO
5 ❑ Individual Health Insurance
6 ❑ Group Health Insurance
7 ❑ National Health Insurance (non-US)
8 ❑ V.A./Military
9 ❑ Other, specify: _____

913. (*U.S. patients only*) Type of fee reimbursement:

1 ❑ Fee for service
2 ❑ Capitation
7 ❑ Other, specify: _____
8 ❑ Unknown

914. Which category best describes patient's occupation?
If not currently employed, which best describes patient's LAST job? (check only one)

1 ❑ Professional, Technical, & Related Occupations (teacher/professor, nurse, lawyer, physician or engineer)
2 ❑ Manager, Administrator or Proprietor (sales manager, real estate agent, or postmaster)
3 ❑ Clerical & Related Occupations (secretary, clerk, or mail carrier)
4 ❑ Sales Occupation (salesperson, demonstrator, agent or broker)
5 ❑ Service Occupation (police, cook or hairdresser)
6 ❑ Skilled crafts & Related Occupations (carpenter, repairer or telephone line worker)
7 ❑ Equipment or Vehicle Operator & Related Occupations (driver, railroad brakeman, or sewer worker)
8 ❑ Laborer (helper, longshoreman or warehouse worker)
9 ❑ Farmer (owner, manager, operator, or tenant)
10 ❑ Member of the military
11 ❑ Homemaker
90 ❑ Other, please describe: _____
88 ❑ Unknown

915. (*US patients only*) What is patient's yearly income, earned by all family members living in household, before taxes? (*check one*)

1 ❑ Less than $5,000
2 ❑ $ 5,000 – $9,999
3 ❑ $10,000 – $19,999
4 ❑ $20,000 – $29,999
5 ❑ $30,000 – $39,999
6 ❑ $40,000 – $49,999
7 ❑ $50,000 – $59,999
8 ❑ $60,000 – $79,999
9 ❑ $80,000 and over
88 ❑ Unknown

INSTITUTIONAL INFORMATION

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

(Institutional Unique Blood or Marrow Transplant Identification Number)

Date of transplant for which this form is being completed: [ ][ ] Month [ ][ ] Day [ ][ ] Year

FOR REGISTRY USE ONLY:

I.D. [ ] – [ ][ ][ ][ ] – [ ][ ][ ][ ][ ][ ]

Date received:

Registry: IBMTR ABMTR (circle one)

Date of report: [ ][ ] Month [ ][ ] Day [ ][ ] Year

---

1. Signed: _____ /

Person completing this form / Please print name

2. Date form completed: [ ][ ] Month [ ][ ] Day [ ][ ] Year

3. Name of doctor for correspondence: _____

Institution: _____

Address: _____

_____

_____

_____

Telephone: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

Extension: [ ][ ][ ][ ][ ]

Fax: [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

4. Make reimbursement check payable to: _____

5. Patient or authorized family member/guardian is aware of, and has consented to, the fact that this case is being entered into the Registry database:

_____(physician's initials).

6. A complete report of transplant consists of the following three forms.

Check when complete:

- ❑ A (white) CORE FORM
- ❑ An appropriate (blue or pink) graft-specific insert (Insert ALLOBM, AUTOPB, or AUTOBM)
- ❑ An appropriate (ivory) disease-specific insert (Inserts I through XVI)

INSERT AUTOBM

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

FOR REGISTRY USE ONLY:

I.D. ☐ – ☐☐☐☐ – ☐☐☐☐☐☐

Date received:

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ ☐☐ ☐☐ Month Day Year

Date of report: ☐☐ ☐☐ ☐☐ Month Day Year

Autologous Bone Marrow Collection and Processing

1. Date of bone marrow harvest: ☐☐ ☐☐ ☐☐ Month Day Year

1.2 Did patient receive treatment prior to harvesting to enhance bone marrow collection?

1 ☐ Yes
0 ☐ No

What treatment did patient receive?

1.3 Chemotherapy:

1 ☐ Yes
0 ☐ No

1.4 Growth factors:

1 ☐ Yes
0 ☐ No

	Yes	No	
1.5	1 ☐	0 ☐	G-CSF
1.6	1 ☐	0 ☐	GM-CSF
1.7	1 ☐	0 ☐	Other, specify: _____

1.8 1 ☐ Yes 0 ☐ No Other, specify: _____

2. *For leukemia/lymphoma patients only:*

What was disease state at time of harvest?

1 ☐ First remission
2 ☐ Second remission — **3.** Date of remission: ☐☐ ☐☐ ☐☐ Month Day Year
3 ☐ Third remission
4 ☐ First relapse
5 ☐ Second relapse
7 ☐ Other, specify: _____

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

4. Was bone marrow cryopreserved?

1 ☐ Yes
0 ☐ No

5. Cryopreservative was:
1 ☐ DMSO
2 ☐ Hydroxyethylstarch
7 ☐ Other, specify: _____

Indicate whether or not tumor involvement of bone marrow or circulating cells was detected prior to transplant by each of the indicated methods:

	Detected in circulating cells*			Detected in bone marrow, prior to harvest*			Detected in harvested bone marrow **(before purging)**		
	Yes	No	Not Tested	Yes	No	Not Tested	Yes	No	Not Tested
Routine histopathology	**6.** 1 ☐	0 ☐	7 ☐	**7.** 1 ☐	0 ☐	7 ☐	**8.** 1 ☐	0 ☐	7 ☐
Polymerase chain reaction (PCR)	**9.** 1 ☐	0 ☐	7 ☐	**10.** 1 ☐	0 ☐	7 ☐	**11.** 1 ☐	0 ☐	7 ☐
Other molecular technique	**12.** 1 ☐	0 ☐	7 ☐	**13.** 1 ☐	0 ☐	7 ☐	**14.** 1 ☐	0 ☐	7 ☐
Immunohistochemistry	**15.** 1 ☐	0 ☐	7 ☐	**16.** 1 ☐	0 ☐	7 ☐	**17.** 1 ☐	0 ☐	7 ☐
Cell culture technique	**18.** 1 ☐	0 ☐	7 ☐	**19.** 1 ☐	0 ☐	7 ☐	**20.** 1 ☐	0 ☐	7 ☐
Other, specify: _____	**21.** 1 ☐	0 ☐	7 ☐	**22.** 1 ☐	0 ☐	7 ☐	**23.** 1 ☐	0 ☐	7 ☐

** Refers to detection of tumor cells in circulation or bone marrow in the interval between last chemotherapy and harvest.*

24. Was bone marrow treated to remove malignant cells (purged)?

1 ☐ Yes
0 ☐ No

Which of the following were used for purging?

	Yes	No	
25.	1 ☐	0 ☐	Monoclonal antibody, specify: _____
26.	1 ☐	0 ☐	4-hydroperoxycyclophosphamide (4HC)
27.	1 ☐	0 ☐	Mafosfamide
28.	1 ☐	0 ☐	Other drug, specify: _____
29.	1 ☐	0 ☐	Elutriation
30.	1 ☐	0 ☐	Immunomagnetic column
31.	1 ☐	0 ☐	Toxin, specify: _____
32.	1 ☐	0 ☐	Positive stem cell selection (other than preparation of mononuclear fraction) Specify method: _____
33.	1 ☐	0 ☐	Other, specify: _____

continued on next page

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

Indicate whether or not tumor involvement of harvested bone marrow was detected after purging by each of the indicated methods:

	Yes	No	Not Tested	
34.	1 ☐	0 ☐	7 ☐	Routine histopathology
35.	1 ☐	0 ☐	7 ☐	Polymerase chain reaction (PCR)
36.	1 ☐	0 ☐	7 ☐	Other molecular technique
37.	1 ☐	0 ☐	7 ☐	Immunohistochemistry
38.	1 ☐	0 ☐	7 ☐	Cell culture technique
39.	1 ☐	0 ☐	7 ☐	Other, specify: _____

40. Were cells (or a portion of cells) expanded ex vivo prior to infusion?

1 ☐ Yes
0 ☐ No

41. Days of expansion culture: ☐☐☐

Growth factors used:

	Yes	No	
42.	1 ☐	0 ☐	G-CSF
43.	1 ☐	0 ☐	GM-CSF
44.	1 ☐	0 ☐	IL-2
45.	1 ☐	0 ☐	IL-3
46.	1 ☐	0 ☐	IL-6
47.	1 ☐	0 ☐	SCF
48.	1 ☐	0 ☐	Thrombopoietin
49.	1 ☐	0 ☐	M-CSF
50.	1 ☐	0 ☐	PIXY 321
51.	1 ☐	0 ☐	Other, specify: _____

52. Number of nucleated cells pre-expansion: ☐☐☐.☐ x 10^{10}

53. Number of nucleated cells post-expansion: ☐☐☐.☐ x 10^{10}

54. Total number of nucleated cells infused: ☐☐☐.☐ x 10^{10}

55. Total number of mononucleated cells infused: ☐☐☐.☐ x 10^{10}

56. Were bone marrow progenitor assays done?

1 ☐ Yes
0 ☐ No

57. Number of CD34+ cells infused: ☐☐☐.☐ x 10^{7} -8 ☐ Unknown

INSERT AUTOPB

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

FOR REGISTRY USE ONLY:

I.D. ☐–☐☐☐☐–☐☐☐☐☐☐

Date received:

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ ☐☐ ☐☐ Month Day Year

Date of report: ☐☐ ☐☐ ☐☐ Month Day Year

Autologous Blood Collection and Processing

1. What was the reason for using blood rather than bone marrow for hematopoietic reconstitution?

1 ☐ All patients receive peripheral blood cells, per protocol
2 ☐ Bone marrow involvement with tumor
3 ☐ Prior radiation to pelvis
4 ☐ Inadequate bone marrow cellularity
7 ☐ Other, specify: _____

2. Date of first stem cell collection: ☐☐ ☐☐ ☐☐ Month Day Year

3. Date of last stem cell collection: ☐☐ ☐☐ ☐☐ Month Day Year

4. Number of collections: ☐☐

5. Did patient receive treatment prior to harvesting to enhance stem cell collection?

1 ☐ Yes
0 ☐ No

What treatment did patient receive?

6. Chemotherapy:
1 ☐ Yes
0 ☐ No

7. Growth factors:
1 ☐ Yes
0 ☐ No

	Yes	No	
8.	1 ☐	0 ☐	G-CSF
9.	1 ☐	0 ☐	GM-CSF
10.	1 ☐	0 ☐	Other, specify: _____

11. 1 ☐ Yes 0 ☐ No Other, specify: _____

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

12. *For leukemia/lymphoma patients only:*

What was disease state at time of stem cell collections?

1 ❑ First remission

2 ❑ Second remission — Date of remission: ☐☐ ☐☐ ☐☐ (Month Day Year)

3 ❑ Third remission

4 ❑ First relapse

5 ❑ Second relapse

7 ❑ Other, specify: _____

13. Were cells cryopreserved?

1 ❑ Yes

0 ❑ No

14. Cryopreservative was:

1 ❑ DMSO

2 ❑ Hydroxyethylstarch

7 ❑ Other, specify: _____

Indicate whether or not tumor involvement of bone marrow or circulating cells was detected prior to transplant by each of the indicated methods:

	Detected in circulating cells*			Detected in bone marrow, prior to harvest*			Detected in harvested cells **(before purging)**		
	Yes	No	Not Tested	Yes	No	Not Tested	Yes	No	Not Tested
Routine histopathology	**15.** 1 ❑	0 ❑	7 ❑	**16.** 1 ❑	0 ❑	7 ❑	**17.** 1 ❑	0 ❑	7 ❑
Polymerase chain reaction (PCR)	**18.** 1 ❑	0 ❑	7 ❑	**19.** 1 ❑	0 ❑	7 ❑	**20.** 1 ❑	0 ❑	7 ❑
Other molecular technique	**21.** 1 ❑	0 ❑	7 ❑	**22.** 1 ❑	0 ❑	7 ❑	**23.** 1 ❑	0 ❑	7 ❑
Immunohistochemistry	**24.** 1 ❑	0 ❑	7 ❑	**25.** 1 ❑	0 ❑	7 ❑	**26.** 1 ❑	0 ❑	7 ❑
Cell culture technique	**27.** 1 ❑	0 ❑	7 ❑	**28.** 1 ❑	0 ❑	7 ❑	**29.** 1 ❑	0 ❑	7 ❑
Other, specify: _____	**30.** 1 ❑	0 ❑	7 ❑	**31.** 1 ❑	0 ❑	7 ❑	**32.** 1 ❑	0 ❑	7 ❑

** Refers to detection of tumor cells in circulation or bone marrow in the interval between last chemotherapy and stem cell collection.*

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

33. Were cells treated to remove malignant cells (purged)? 1 ❑ Yes 0 ❑ No

Which of the following were used for purging?

	Yes	No	
34.	1 ❑	0 ❑	Monoclonal antibody, specify: _____
35.	1 ❑	0 ❑	4-hydroperoxycyclophosphamide (4HC)
36.	1 ❑	0 ❑	Mafosfamide
37.	1 ❑	0 ❑	Other drug, specify: _____
38.	1 ❑	0 ❑	Elutriation
39.	1 ❑	0 ❑	Immunomagnetic column
40.	1 ❑	0 ❑	Toxin, specify: _____
41.	1 ❑	0 ❑	Positive stem cell selection (other than preparation of mononuclear fraction) Specify method: _____
42.	1 ❑	0 ❑	Other, specify: _____

Indicate whether or not tumor cells were detected in the graft after purging by each of the indicated methods:

	Yes	No	Not Tested	
43.	1 ❑	0 ❑	7 ❑	Routine histopathology
44.	1 ❑	0 ❑	7 ❑	Polymerase chain reaction (PCR)
45.	1 ❑	0 ❑	7 ❑	Other molecular technique
46.	1 ❑	0 ❑	7 ❑	Immunohistochemistry
47.	1 ❑	0 ❑	7 ❑	Cell culture technique
48.	1 ❑	0 ❑	7 ❑	Other, specify: _____

49. Were cells expanded ex vivo prior to infusion?

1 ❑ Yes
0 ❑ No

50. Days of expansion culture: ☐☐☐

Growth factors used:

	Yes	No	
51.	1 ❑	0 ❑	G-CSF
52.	1 ❑	0 ❑	GM-CSF
53.	1 ❑	0 ❑	IL-2
54.	1 ❑	0 ❑	IL-3
55.	1 ❑	0 ❑	IL-6
56.	1 ❑	0 ❑	SCF
57.	1 ❑	0 ❑	Thrombopoietin
58.	1 ❑	0 ❑	M-CSF
59.	1 ❑	0 ❑	PIXY 321
60.	1 ❑	0 ❑	Other, specify: _____

61. Number of nucleated cells pre-expansion: ☐☐☐.☐ x 10^{10}

62. Number of nucleated cells post-expansion: ☐☐☐.☐ x 10^{10}

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

63. Total number of nucleated cells infused: ☐☐☐.☐ x 10^{10}

64. Total number of mononucleated cells infused: ☐☐☐.☐ x 10^{10}

65. Were progenitor cell assays done?

1 ☐ Yes

0 ☐ No

66. Number of CD34+ cells infused: ☐☐☐.☐ x 10^{7} -8 ☐ Unknown

INSERT VIII
Breast Cancer

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐
(Institutional Unique Blood or Marrow Transplant Identification Number)

Date of transplant for which this form is being completed: ☐☐ Month ☐☐ Day ☐☐ Year

FOR REGISTRY USE ONLY:
I.D. ☐-☐☐☐☐-☐☐☐☐☐☐
Date received:

Registry: IBMTR ABMTR (circle one)

Date of report: ☐☐ Month ☐☐ Day ☐☐ Year

Pretransplant Information

**** If this is a report of a second (or subsequent) transplant, check here ☐ and go to Q.168***

1. Date of pathologic diagnosis of breast cancer: ☐☐ Month ☐☐ Year
Append copy of pathology report if available.

If transplant was done after occurence of a second primary breast cancer, report staging and treatment [Q.1-75] of each primary separately by copying pages 1-4.

2. Stage of breast cancer at diagnosis:

0 ☐ In situ
1 ☐ I - $T_1 N_0 M_0$
2 ☐ II - $T_{0,1} N_1 M_0$ or $T_2 N_{0,1} M_0$ or $T_3 N_0 M_0$
3 ☐ IIIA - $T_{0-2} N_2 M_0$ or $T_3 N_{1-2} M_0$
4 ☐ IIIB - $T_4 N_{Any} M_0$, $T_{Any} N_3 M_0$, Inflammatory
5 ☐ IV - $T_{Any} N_{Any} M_1$
8 ☐ Unknown

3. Breast cancer histology at diagnosis:

1 ☐ Invasive/infiltrating ductal
2 ☐ Invasive lobular
3 ☐ Inflammatory
4 ☐ Other, specify: _____
8 ☐ Unknown

4. Location of breast cancer at diagnosis:

1 ☐ Right breast
2 ☐ Left breast
3 ☐ Bilateral

5. Menopausal status at diagnosis:

1 ☐ Premenopausal
2 ☐ Postmenopausal
7 ☐ Not applicable, male patient
8 ☐ Unknown

6. Age at menopause: ☐☐ years

7. Did patient have a history of prior cancer (other than breast cancer)?

1 ☐ Yes
0 ☐ No

8. Cite prior disease:

1 ☐ Hodgkin lymphoma
2 ☐ Non-Hodgkin lymphoma
7 ☐ Other, specify: _____

9. Date of diagnosis of prior cancer: ☐☐ Month ☐☐ Year

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10. Were metastases (other than ipsilateral axillary lymph nodes) present at diagnosis?

1 ☐ Yes
0 ☐ No

	Yes	No	Unknown	
11.	1 ☐	0 ☐	8 ☐	Bone
12.	1 ☐	0 ☐	8 ☐	Bone marrow
13.	1 ☐	0 ☐	8 ☐	Lung
14.	1 ☐	0 ☐	8 ☐	Liver
15.	1 ☐	0 ☐	8 ☐	Skin
16.	1 ☐	0 ☐	8 ☐	Chest wall
17.	1 ☐	0 ☐	8 ☐	Other lymph nodes, specify site: _____
18.	1 ☐	0 ☐	8 ☐	Other, specify: _____

19. Did patient receive neoadjuvant treatment (includes chemotherapy, hormones and/or radiation) prior to definitive surgery?

1 ☐ Yes
0 ☐ No — Go to Q. 38

Neoadjuvant Treatment

Size of primary tumor (largest diameter before neoadjuvant treatment)

20. Was tumor multicentric?

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

Give size of largest tumor in Q.21 – 22

21. Clinical size: ☐☐ cm -7 ☐ Not measurable -8 ☐ Unknown

22. Radiographic size: ☐☐ cm -7 ☐ Not measurable -8 ☐ Unknown

23. Did patient receive neoadjuvant **chemotherapy**?

1 ☐ Yes
0 ☐ No

Specify chemotherapy:

	Yes	No	
24.	1 ☐	0 ☐	Adriamycin alone
25.	1 ☐	0 ☐	CAF
26.	1 ☐	0 ☐	CMF
27.	1 ☐	0 ☐	AFM
28.	1 ☐	0 ☐	Other, specify: _____

29. Number of cycles: ☐

30. Did patient receive neoadjuvant **hormone therapy**?

1 ☐ Yes
0 ☐ No

Specify hormones:

	Yes	No	
31.	1 ☐	0 ☐	Tamoxifen
32.	1 ☐	0 ☐	Other, specify: _____

33. Duration of pre-surgical treatment was: ☐☐.☐ mos.

Continued on next page

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34. Did patient receive neoadjuvant **radiation therapy**?

1 ☐ Yes
0 ☐ No

35. Specify radiation field: _____

36. Total dose: ☐☐☐☐ cGy (rads)

37. Best clinical response (at time of surgery) to neoadjuvant treatment:

1 ☐ Complete response
2 ☐ Partial response
3 ☐ Stable disease
4 ☐ Progressive disease
8 ☐ Not evaluable, specify why not evaluable: _____

38. Did patient have surgery as part of initial management (include surgery done after neoadjuvant treatment)?

1 ☐ Yes
0 ☐ No

39. Type of surgery was:

1 ☐ Mastectomy
2 ☐ Lumpectomy
7 ☐ Other, specify: _____

Size of primary tumor at time of definitive surgery; or, if surgery was not done, prior to initial non-surgical treatment

40. Was tumor multicentric?

1 ☐ Yes
0 ☐ No

Give size of largest tumor in Q.41 – 43

41. Clinical size: ☐☐ cm -8 ☐ Unknown

42. Radiographic size: ☐☐ cm -8 ☐ Unknown

43. Pathologic size: ☐☐ cm -8 ☐ Unknown

44. How many axillary nodes were examined? ☐☐ -8 ☐ Unknown

45. How many axillary nodes were positive for breast cancer? ☐☐ -8 ☐ Unknown

46. Were estrogen receptor assays done?

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

47. Results:

1 ☐ Positive 3 ☐ Borderline
2 ☐ Negative 8 ☐ Unknown

48. Actual value if available (specify units): ☐☐☐☐

49. Units:

1 ☐ fmol/mg
7 ☐ Other, specify: _____

50. Were progesterone receptor assays done?

1 ☐ Yes
0 ☐ No
8 ☐ Unknown

51. Results:

1 ☐ Positive 3 ☐ Borderline
2 ☐ Negative 8 ☐ Unknown

52. Actual value if available (specify units): ☐☐☐☐

53. Units:

1 ☐ fmol/mg
7 ☐ Other, specify: _____

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54. Did patient receive radiation, chemotherapy and/or hormone treatment (excluding neoadjuvant) after definitive surgery as part of initial management?

1 ☐ Yes
0 ☐ No

55. Did patient receive radiation treatment?

1 ☐ Yes
0 ☐ No

Radiation field:

	Yes	No	
56.	1 ☐	0 ☐	local/regional
57.	1 ☐	0 ☐	sites of distant metastatic disease
58.	1 ☐	0 ☐	Other, specify: _____

59. Total dose: ☐☐☐☐ cGy (rads)

60. Did patient receive hormones?

1 ☐ Yes
0 ☐ No

Specify hormones:

	Yes	No	
61.	1 ☐	0 ☐	Tamoxifen
62.	1 ☐	0 ☐	Other, specify: _____

63. Date started: ☐☐ ☐☐ Month Year

64. Date ended: ☐☐ ☐☐ Month Year

65. Did patient receive chemotherapy?

1 ☐ Yes
0 ☐ No

66. Reason for chemotherapy:
1 ☐ Adjuvant
2 ☐ For metastatic disease — Go to Q.79

Chemotherapy given:

	Yes	No	
67.	1 ☐	0 ☐	CMF
68.	1 ☐	0 ☐	CAF
69.	1 ☐	0 ☐	Adriamycin-containing regimen
70.	1 ☐	0 ☐	Taxol alone
71.	1 ☐	0 ☐	Taxol plus other drugs
72.	1 ☐	0 ☐	Other chemotherapy, specify: _____

73. Number of cycles: ☐☐ -8 ☐ Unknown

74. Date started: ☐☐ ☐☐ Month Year

75. Date ended: ☐☐ ☐☐ Month Year

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76. Did breast cancer recur?

1 ☐ Yes — **77.** Date: ☐☐ ☐☐ (Month Year)

0 ☐ No — **78.** Site(s): _____

79. Did patient receive treatment for persistent, recurrent or metastatic disease? 1 ☐ Yes 0 ☐ No

Regimen	Date Started	Date Stopped	Number cycles (chemotherapy)	Total dose (radiation)	Non-bone Response (see below)	Bone Response (see below)	Date Relapse/ Progression
1st	**80.** ☐☐ ☐☐ (Month Year)	**81.** ☐☐ ☐☐ (Month Year)	**82.** ☐☐	**83.** ☐☐☐☐ cGy (rads)	**84.** ☐	**85.** ☐	**86.** ☐☐ ☐☐ (Month Year)
2nd	**97.** ☐☐ ☐☐ (Month Year)	**98.** ☐☐ ☐☐ (Month Year)	**99.** ☐☐	**100.** ☐☐☐☐ cGy (rads)	**101.** ☐	**102.** ☐	**103.** ☐☐ ☐☐ (Month Year)
3rd	**114.** ☐☐ ☐☐ (Month Year)	**115.** ☐☐ ☐☐ (Month Year)	**116.** ☐☐	**117.** ☐☐☐☐ cGy (rads)	**118.** ☐	**119.** ☐	**120.** ☐☐ ☐☐ (Month Year)

Treatment, specify all drugs given:

	Yes	No							
	1 ☐	0 ☐	Adriamycin	1 ☐	0 ☐	Methotrexate	1 ☐	0 ☐	Thiotepa
	1 ☐	0 ☐	Cytoxan	1 ☐	0 ☐	Mitoxantrone	1 ☐	0 ☐	Vinblastine
	1 ☐	0 ☐	Cisplatin	1 ☐	0 ☐	Taxol	1 ☐	0 ☐	Other, specify:
	1 ☐	0 ☐	5-fluorouracil (5-FU)						

	Yes	No							
87.	1 ☐	0 ☐	Adriamycin	**91.** 1 ☐	0 ☐	Methotrexate	**94.** 1 ☐	0 ☐	Thiotepa
88.	1 ☐	0 ☐	Cytoxan	**92.** 1 ☐	0 ☐	Mitoxantrone	**95.** 1 ☐	0 ☐	Vinblastine
89.	1 ☐	0 ☐	Cisplatin	**93.** 1 ☐	0 ☐	Taxol	**96.** 1 ☐	0 ☐	Other, specify:
90.	1 ☐	0 ☐	5-fluorouracil (5-FU)						

	Yes	No							
104.	1 ☐	0 ☐	Adriamycin	**108.** 1 ☐	0 ☐	Methotrexate	**111.** 1 ☐	0 ☐	Thiotepa
105.	1 ☐	0 ☐	Cytoxan	**109.** 1 ☐	0 ☐	Mitoxantrone	**112.** 1 ☐	0 ☐	Vinblastine
106.	1 ☐	0 ☐	Cisplatin	**110.** 1 ☐	0 ☐	Taxol	**113.** 1 ☐	0 ☐	Other, specify:
107.	1 ☐	0 ☐	5-fluorouracil (5-FU)						

	Yes	No							
121.	1 ☐	0 ☐	Adriamycin	**125.** 1 ☐	0 ☐	Methotrexate	**128.** 1 ☐	0 ☐	Thiotepa
122.	1 ☐	0 ☐	Cytoxan	**126.** 1 ☐	0 ☐	Mitoxantrone	**129.** 1 ☐	0 ☐	Vinblastine
123.	1 ☐	0 ☐	Cisplatin	**127.** 1 ☐	0 ☐	Taxol	**130.** 1 ☐	0 ☐	Other, specify:
124.	1 ☐	0 ☐	5-fluorouracil (5-FU)						

Non-bone response codes:
1 = CR
2 = PR
3 = stable disease
4 = progressive disease

Bone response codes:
1 = no prior bone disease
2 = symptomatic improvement, no progression
3 = symptomatic and radiographic (not bone scan only) improvement
4 = no response
5 = progressive disease
6 = not evaluable (radiographic data not available)

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Regimen	Date Started	Date Stopped	Number cycles (chemotherapy)	Total dose (radiation)	Non-bone Response (see below)	Bone Response (see below)	Date Relapse/ Progression
4th	131. ☐☐ Month ☐☐ Year	132. ☐☐ Month ☐☐ Year	133. ☐☐	134. ☐☐☐☐ cGy (rads)	135. ☐	136. ☐	137. ☐☐ Month ☐☐ Year

Treatment, specify all drugs given:

	Yes	No							
138.	1 ☐	0 ☐	Adriamycin	142.	1 ☐	0 ☐	Methotrexate	145.	1 ☐ 0 ☐ Thiotepa
139.	1 ☐	0 ☐	Cytoxan	143.	1 ☐	0 ☐	Mitoxantrone	146.	1 ☐ 0 ☐ Vinblastine
140.	1 ☐	0 ☐	Cis-platin	144.	1 ☐	0 ☐	Taxol	147.	1 ☐ 0 ☐ Other, specify:
141.	1 ☐	0 ☐	5-fluorouracil (5-FU)						

Regimen	Date Started	Date Stopped	Number cycles (chemotherapy)	Total dose (radiation)	Non-bone Response (see below)	Bone Response (see below)	Date Relapse/ Progression
5th	148. ☐☐ Month ☐☐ Year	149. ☐☐ Month ☐☐ Year	150. ☐☐	151. ☐☐☐☐ cGy (rads)	152. ☐	153. ☐	154. ☐☐ Month ☐☐ Year

Treatment, specify all drugs given:

	Yes	No							
155.	1 ☐	0 ☐	Adriamycin	159.	1 ☐	0 ☐	Methotrexate	162.	1 ☐ 0 ☐ Thiotepa
156.	1 ☐	0 ☐	Cytoxan	160.	1 ☐	0 ☐	Mitoxantrone	163.	1 ☐ 0 ☐ Vinblastine
157.	1 ☐	0 ☐	Cis-platin	161.	1 ☐	0 ☐	Taxol	164.	1 ☐ 0 ☐ Other, specify:
158.	1 ☐	0 ☐	5-fluorouracil (5-FU)						

Non-bone response codes:
1 = CR
2 = PR
3 = stable disease
4 = progressive disease

Bone response codes:
1 = no prior bone disease
2 = symptomatic improvement, no progression
3 = symptomatic and radiographic (not bone scan only) improvement
4 = no response
5 = progressive disease
6 = not evaluable (radiographic data not available)

What was the total dose of anthracyclines prior to start of high-dose therapy (conditioning)?

165. Doxorubicin: (Adriamycin) ☐☐☐ mg/m² -8 ☐ Unknown -7 ☐ Not given

166. Mitoxantrone: ☐☐☐ mg/m² -8 ☐ Unknown -7 ☐ Not given

167. Other anthracycline, specify: _____ ☐☐☐ mg/m² -8 ☐ Unknown -7 ☐ Not given

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168. Was bone marrow biopsy done prior to high-dose conditioning?

1 ☐ Yes
0 ☐ No

169. Date of most recent biopsy ☐☐ ☐☐ ☐☐
Month Day Year

170. Was breast cancer present?

1 ☐ Yes
0 ☐ No

How was it detected?

	Yes	No	Not tested	
171.	1 ☐	0 ☐	7 ☐	Routine histopathology
172.	1 ☐	0 ☐	7 ☐	PCR (polymerase chain reaction)
173.	1 ☐	0 ☐	7 ☐	Other molecular technique
174.	1 ☐	0 ☐	7 ☐	Immunohistochemistry
175.	1 ☐	0 ☐	7 ☐	Cell culture technique
176.	1 ☐	0 ☐	7 ☐	Other, specify: _____

177. Did patient ever have bone marrow involvement with breast cancer other than involvement indicated in Q.168?

1 ☐ Yes
0 ☐ No

How was it detected?

	Yes	No	Not tested	
178.	1 ☐	0 ☐	7 ☐	Routine histopathology
179.	1 ☐	0 ☐	7 ☐	PCR (polymerase chain reaction)
180.	1 ☐	0 ☐	7 ☐	Other molecular technique
181.	1 ☐	0 ☐	7 ☐	Immunohistochemistry
182.	1 ☐	0 ☐	7 ☐	Cell culture technique
183.	1 ☐	0 ☐	7 ☐	Other, specify: _____

184. What was status of disease immediately prior to start of conditioning?

1 ☐ Complete response - no evidence of disease
2 ☐ Complete response with exception of bone scan abnormalities of unknown significance
3 ☐ Partial response
4 ☐ Stable
5 ☐ Progressive disease

Indicate all sites of disease involvement:

	At any time between diagnosis and transplant				Immediately prior to start of conditioning			
		Yes	No	Unknown		Yes	No	Unknown
Breast	**185.1.**	1 ☐	0 ☐	8 ☐	**185.2.**	1 ☐	0 ☐	8 ☐
Chest wall	**186.1.**	1 ☐	0 ☐	8 ☐	**186.2.**	1 ☐	0 ☐	8 ☐
Bone - symptomatic	**187.1.**	1 ☐	0 ☐	8 ☐	**187.2.**	1 ☐	0 ☐	8 ☐
Bone - radiographic	**188.1.**	1 ☐	0 ☐	8 ☐	**188.2.**	1 ☐	0 ☐	8 ☐
Axillary lymph nodes	**189.1.**	1 ☐	0 ☐	8 ☐	**189.2.**	1 ☐	0 ☐	8 ☐
Other lymph nodes	**190.1.**	1 ☐	0 ☐	8 ☐	**190.2.**	1 ☐	0 ☐	8 ☐
Brain	**191.1.**	1 ☐	0 ☐	8 ☐	**191.2.**	1 ☐	0 ☐	8 ☐
Lung	**192.1.**	1 ☐	0 ☐	8 ☐	**192.2.**	1 ☐	0 ☐	8 ☐
Pleura	**193.1.**	1 ☐	0 ☐	8 ☐	**193.2.**	1 ☐	0 ☐	8 ☐
Liver	**194.1.**	1 ☐	0 ☐	8 ☐	**194.2.**	1 ☐	0 ☐	8 ☐
Skin	**195.1.**	1 ☐	0 ☐	8 ☐	**195.2.**	1 ☐	0 ☐	8 ☐
Other, specify:	**196.1.**	1 ☐	0 ☐	8 ☐	**196.2.**	1 ☐	0 ☐	8 ☐

_____

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197. What was sensitivity of breast cancer to chemotherapy prior to conditioning? *(Response to last chemotherapy given prior to transplant; chemotherapy must include ≥ 2 cycles treatment given ≤ 6 months prior to transplant)*

1 ☐ Sensitive: ≥ 50% reduction in bidimensional diameter of all disease sites with no new sites of disease
2 ☐ Resistant: < 50% reduction in diameter of all disease sites or development of new disease sites
3 ☐ Untreated
8 ☐ Unknown

Outcome

198. What was patient's best response to transplant excluding planned posttransplant treatment?

1 ☐ Complete response: complete disappearance of all known disease for ≥ 4 weeks
2 ☐ Complete response with persistent bone scan/x-ray abnormalities of unknown significance
3 ☐ Partial response: ≥ 50% reduction in greatest diameter of all sites of known disease and no new sites of disease for ≥ 4 weeks
4 ☐ No response: < 50% reduction in greatest diameter of all sites of known disease and no new sites of disease
5 ☐ Progressive disease: increase in size of sites of known disease or new sites of disease
6 ☐ Not evaluable, toxic death
7 ☐ Not evaluable, other reason, specify: _____

199. Was planned treatment (treatment before progressive disease) given posttransplant?

1 ☐ Yes
0 ☐ No → Go to Q.207

200. Was disease restaged prior to planned posttransplant treatment?

1 ☐ Yes
0 ☐ No

Specify treatment given whether restaged or not:

	Yes	No	
201.	1 ☐	0 ☐	Chemotherapy, specify: _____
202.	1 ☐	0 ☐	Hormone therapy, specify: _____
203.	1 ☐	0 ☐	Radiation therapy, specify: _____
204.	1 ☐	0 ☐	Immune therapy, specify: _____
205.	1 ☐	0 ☐	Other, specify: _____

206. What was patient's best response to transplant including planned posttransplant treatment?

1 ☐ Complete response: complete disappearance of all known disease for ≥ 4 weeks
2 ☐ Complete response with persistent bone scan/x-ray abnormalities of unknown significance
3 ☐ Partial response: ≥ 50% reduction in greatest diameter of all sites of known disease and no new sites of disease for ≥ 4 weeks
4 ☐ No response: < 50% reduction in greatest diameter of all sites of known disease and no new sites of disease
5 ☐ Progressive disease: increase in size of sites of known disease or new sites of disease
6 ☐ Not evaluable, toxic death
7 ☐ Not evaluable, other reason, specify: _____

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207. Status of breast cancer: (*at time of this report or at time of death*)

1 ☐ Free of breast cancer; no recurrence posttransplant

2 ☐ Free of breast cancer except for persistent scan abnormalities of unknown significance, no recurrence posttransplant

3 ☐ Persistent breast cancer without progression (*never achieved complete response*)

4 ☐ Progressive disease (*never achieved complete response*)

Date of progression ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

5 ☐ Recurrent disease (relapse after complete response)

Date of recurrence ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

6 ☐ Free of breast cancer after posttransplant recurrence

Date of recurrence ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

7 ☐ Not evaluable; explain: _____

First site(s) of progression/recurrence:

	Yes	No	
208.	1 ☐	0 ☐	Lymph node
209.	1 ☐	0 ☐	Bone marrow
210.	1 ☐	0 ☐	CNS
211.	1 ☐	0 ☐	Liver
212.	1 ☐	0 ☐	Lung
213.	1 ☐	0 ☐	Local
214.	1 ☐	0 ☐	Contralateral breast
215.	1 ☐	0 ☐	Other, specify: _____

216. Date status established: ☐☐ ☐☐ ☐☐
Month Day Year

FOLLOW-UP CORE FORM

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

FOR REGISTRY USE ONLY:

I.D. ☐ – ☐☐☐☐ – ☐☐☐☐☐☐

Date received:

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ Month ☐☐ Day ☐☐ Year

Date of report: ☐☐ Month ☐☐ Day ☐☐ Year

IBMTR International Bone Marrow Transplant Registry

IBMTR/ABMTR

Series 095 Reporting Forms

ABMTR North America Autologous Blood & Marrow Transplant Registry

Follow-up Information

For living patients, submit follow-up data every 12 months from date of transplant. If patient died since last report, indicate findings present at time of death. For patients lost to follow-up since last report, submit last known information. If another transplant was done since last report, provide information only until date of conditioning for subsequent transplant. If patient received peripheral blood leukocytes from original allogeneic donor since last report to treat relapse, lymphoproliferative disorder, viral infection or graft failure, provide information only until date of infusion (see Q. 33 of this report).

1. Date of last report: ☐☐ Month ☐☐ Day ☐☐ Year

2. Patient birthdate: ☐☐ Month ☐☐ Day ☐☐ Year

3. Date of last actual contact with patient to determine medical status for this report: ☐☐ Month ☐☐ Day ☐☐ Year

Survival and Functional Status

4. Was patient alive on the day of last contact?

1 ☐ Yes → **5.** *If the patient is 16 years of age or older, complete the Karnofsky Scale. If the patient is younger than 16 years of age, complete the Lansky Scale.*

0 ☐ No → Go to Q. 15

Karnofsky Scale (age ≥16 yrs)

Select phrase which best describes activity status:

Able to carry on normal activity; no special care is needed.

- ☐ 100 Normal; no complaints; no evidence of disease
- ☐ 90 Able to carry on normal activity
- ☐ 80 Normal activity with effort

Unable to work; able to live at home, care for most personal needs; a varying amount of assistance is needed.

- ☐ 70 Cares for self; unable to carry on normal activity or to do active work
- ☐ 60 Requires occasional assistance but is able to care for most needs
- ☐ 50 Requires considerable assistance and frequent medical care

Unable to care for self; requires equivalent of institutional or hospital care; disease may be progressing rapidly.

- ☐ 40 Disabled; requires special care and assistance
- ☐ 30 Severely disabled; hospitalization indicated, although death not imminent
- ☐ 20 Very sick; hospitalization necessary
- ☐ 10 Moribund; fatal process progressing rapidly

Lansky Scale (age <16 yrs)

Select phrase which best describes the activity status:

Normal range.

- ☐ 100 Fully active
- ☐ 90 Minor restriction in physically strenuous play
- ☐ 80 Restricted in strenuous play, tires more easily, otherwise active

Mild to moderate restriction.

- ☐ 70 Both greater restrictions of, and less time spent in, active play
- ☐ 60 Ambulatory up to 50% of time, limited active play with assistance/supervision
- ☐ 50 Considerable assistance required for any active play; fully able to engage in quiet play

Moderate to severe restriction.

- ☐ 40 Able to initiate quiet activities
- ☐ 30 Needs considerable assistance for quiet activity
- ☐ 20 Limited to very passive activity initiated by others (i.e., TV)
- ☐ 10 Completely disabled, not even passive play

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6. Patient currently attends school:

1 ❑ Yes
0 ❑ No

7. 1 ❑ Part-time 2 ❑ Full-time 8 ❑ Unknown whether part-time or full-time

8. Date returned to school: ☐☐ (Month) ☐☐ (Year) or ❑ Reported previously

9. Patient was employed outside the home prior to current illness:

1 ❑ Yes
0 ❑ No

10. Patient has been employed outside the home since transplant:

1 ❑ Yes
0 ❑ No

11. Date returned to work: ☐☐ (Month) ☐☐ (Year) or ❑ Reported previously

12. Patient able to work but is not employed:

1 ❑ Yes
0 ❑ No

13. Patient has resumed all household activities:

1 ❑ Yes
0 ❑ No

14. Approximate date resumed all activities: ☐☐ (Month) ☐☐ (Year) or ❑ Reported previously

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15. Did patient receive a blood or marrow infusion since the date of last report?
(other than peripheral blood leukocytes or T-lymphocytes from original allogeneic donor)

1 ❑ Yes
0 ❑ No

16. Date of subsequent infusion: ☐☐ ☐☐ ☐☐
Month Day Year

17. Reason for subsequent infusion:

1 ❑ No engraftment
2 ❑ Partial engraftment
3 ❑ Late graft failure
4 ❑ Persistent malignancy
5 ❑ Relapse
6 ❑ Planned second transplant, per protocol
7 ❑ Other, specify: _____

18. Type of graft:

1 ❑ Allogeneic, related
2 ❑ Allogeneic, unrelated
3 ❑ Autologous

19. Donor
1 ❑ Same donor
2 ❑ Different donor
3 ❑ Not applicable, initial transplant was autologous

Source of cells:

	Yes	No	
20.	1 ❑	0 ❑	Cryopreserved
21.	1 ❑	0 ❑	Bone marrow
22.	1 ❑	0 ❑	Peripheral blood
23.	1 ❑	0 ❑	Umbilical cord blood
24.	1 ❑	0 ❑	Fetal tissue
25.	1 ❑	0 ❑	Other, specify: _____

Answers to all questions in this report should reflect clinical status immediately prior to start of conditioning for subsequent infusion. ***A separate report covering the subsequent transplant must be submitted.***

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26. *Allografts only:* Has patient received an infusion of peripheral blood leukocytes or T-lymphocytes from the original donor since date of last report?

1 ☐ Yes
0 ☐ No

27. Date first infusion given: ☐☐ ☐☐ ☐☐ Month Day Year

28. Patient weight within 2 weeks of first infusion: ☐☐☐.☐ kg

29. Total number of infusions: ☐☐

30. Total dose of mononuclear cells infused: ☐☐☐.☐ x 10^{10}

31. Were cells manipulated prior to infusion?

1 ☐ Yes
0 ☐ No

32. Indicate method:

Yes	No	
1 ☐	0 ☐	T-cell depletion
1 ☐	0 ☐	CD34 selection
1 ☐	0 ☐	Other, specify: _____

33. Indication for the infusion(s) of donor cells:

1 ☐ Prophylaxis against B-cell lymphoproliferative disorder or viral infection
2 ☐ Prophylaxis against relapse
3 ☐ Treatment of relapse
4 ☐ Treatment of B-cell lymphoproliferative disorder
5 ☐ Treatment of viral infection, specify: _____
6 ☐ Graft failure
7 ☐ Other, specify: _____

If answers 3 – 7 were selected, then answers to all questions in this report should reflect clinical status immediately prior to infusion. ***This is considered a transplant and a separate report covering this infusion and post-infusion events must be submitted.***

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Hematopoietic Reconstitution

34. Has patient received hematopoietic growth factors or cytokines since last report? 1 ☐ Yes 0 ☐ No

Coding for Indication of Therapy (below)
1. Intervention for delay/decline in Absolute Neutrophil Count (ANC)
2. Intervention for delay/decline in platelets
3. Intervention for delay/decline in both ANC and platelets
4. Intervention for delay/decline in red blood cell counts
5. Anti-leukemic or tumor agent to prevent relapse
6. Anti-leukemic or tumor agent to treat relapse
7. Other indication

Specify agents given:

	Yes	No	Date Started Month	Day	Year	Date Stopped Month	Day	Year	Indication
G-CSF	35. 1 ☐	0 ☐	36. ☐☐	☐☐	☐☐	37. ☐☐	☐☐	☐☐	38. ☐
GM-CSF	39. 1 ☐	0 ☐	40. ☐☐	☐☐	☐☐	41. ☐☐	☐☐	☐☐	42. ☐
Erythropoietin	43. 1 ☐	0 ☐	44. ☐☐	☐☐	☐☐	45. ☐☐	☐☐	☐☐	46. ☐
Thrombopoietin	47. 1 ☐	0 ☐	48. ☐☐	☐☐	☐☐	49. ☐☐	☐☐	☐☐	50. ☐
Interleukin-2	51. 1 ☐	0 ☐	52. ☐☐	☐☐	☐☐	53. ☐☐	☐☐	☐☐	54. ☐
Interleukin-3	55. 1 ☐	0 ☐	56. ☐☐	☐☐	☐☐	57. ☐☐	☐☐	☐☐	58. ☐
Interleukin-6	59. 1 ☐	0 ☐	60. ☐☐	☐☐	☐☐	61. ☐☐	☐☐	☐☐	62. ☐
PIXY-321	63. 1 ☐	0 ☐	64. ☐☐	☐☐	☐☐	65. ☐☐	☐☐	☐☐	66. ☐
Stem Cell Factor (SCF)	67. 1 ☐	0 ☐	68. ☐☐	☐☐	☐☐	69. ☐☐	☐☐	☐☐	70. ☐
Interferon-alpha	71. 1 ☐	0 ☐	72. ☐☐	☐☐	☐☐	73. ☐☐	☐☐	☐☐	74. ☐
Interferon-gamma	75. 1 ☐	0 ☐	76. ☐☐	☐☐	☐☐	77. ☐☐	☐☐	☐☐	78. ☐
Blinded growth factor trial, specify agent(s) being studied: _____	79. 1 ☐	0 ☐	80. ☐☐	☐☐	☐☐	81. ☐☐	☐☐	☐☐	82. ☐
Other, specify: _____	83. 1 ☐	0 ☐	84. ☐☐	☐☐	☐☐	85. ☐☐	☐☐	☐☐	86. ☐

87. Did patient receive other courses of growth factors or cytokines since last report?

1 ☐ Yes — *Photocopy Q.35-86 and answer for each additional course given.*
0 ☐ No
8 ☐ Unknown

NOTE: *A new course includes starting a new agent, restarting a previously administered agent for a new indication or restarting a previously administered agent for the same indication but ≥ 30 days after discontinuing the agent.*

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Granulopoiesis

88. Did patient achieve an initial hematopoietic recovery (ANC ≥ 500/mm³ for 3 consecutive days) since last report?

1 ❑ Yes

89. Date ANC ≥ 500/mm³: *(First of 3 consecutive days)* ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

90. Was ANC ≥ 1000/mm³ achieved and sustained for 3 consecutive days?

1 ❑ Yes

91. Date achieved: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown *(first of 3 consecutive days)*

0 ❑ No → Go to Q. 92

2 ❑ No, patient's initital hematopoietic recovery was recorded on a previous report → Go to Q. 92

3 ❑ No, patient has never achieved an ANC ≥ 500/mm³ for three consecutive days and there is no evidence of recurrent disease → Go to Q. 96

4 ❑ No, patient has never achieved an ANC ≥ 500/mm³ for three consecutive days and there was documented persistent malignant disease posttransplant → Go to Q. 96

92. Following initial hematopoietic recovery (ANC ≥ 500/mm³ for three consecutive days) did the patient experience a subsequent decline in ANC to < 500/mm³ for greater than three days since last report?

1 ❑ Yes

93. Date of decline in ANC to < 500/mm³ for greater than 3 days: *(First of 3 days that ANC declined)* ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

94. Did patient recover and maintain ANC ≥ 500/mm³ following the decline?

1 ❑ Yes

95. Date of ANC recovery: ☐☐ Month ☐☐ Day ☐☐ Year ❑ Date unknown

0 ❑ No → Go to Q. 96

0 ❑ No → Go to Q. 117

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Suspected etiology of failure to achieve ANC > 500/mm³ or of a decline in ANC:

96. Persistent disease or relapse:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

97. Graft versus host disease:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

98. Immune-mediated rejection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

99. Non-viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

100. Suspected viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus suspected:

	Yes	No	
101.	1 ❑	0 ❑	Cytomegalovirus (CMV)
102.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
103.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
104.	1 ❑	0 ❑	Varicella
105.	1 ❑	0 ❑	Other, specify: _____

106. Documented viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus involved:

	Yes	No	
107.	1 ❑	0 ❑	Cytomegalovirus (CMV)
108.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
109.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
110.	1 ❑	0 ❑	Varicella
111.	1 ❑	0 ❑	Other, specify: _____

112. Drugs:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

	Yes	No	
113.	1 ❑	0 ❑	Ganciclovir
114.	1 ❑	0 ❑	Bactrim, Septra, Trimethoprim-sulfamethoxazole
115.	1 ❑	0 ❑	Other, specify: _____

116. Etiology undetermined:
- 1 ❑ Yes
- 0 ❑ No

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Megakaryopoiesis

*The following questions relate to **initial** platelet recovery. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory results.*

117. Did recipient achieve an **initial** platelet count of ≥ 20 x 10^9/L since last report?

1 ❑ Yes — Go to Q. 118
2 ❑ No, recipient achieved a platelet count of ≥ 20 x 10^9/L but < 50 x 10^9/L prior to last report — Go to Q. 119
3 ❑ No, recipient achieved a platelet count of ≥ 50 x 10^9/L but < 100 x 10^9/L prior to last report — Go to Q. 121
4 ❑ No, recipient achieved a platelet count of ≥ 100 x 10^9/L prior to last report — Go to Q. 125
0 ❑ No, recipient never achieved a platelet count of ≥ 20 x 10^9/L — Go to Q. 123

118. Date platelets ≥ 20 x 10^9/L: ☐☐ ☐☐ ☐☐ ❑ Date unknown
Month Day Year

119. Was a platelet count of ≥ 50 x 10^9/L achieved?

1 ❑ Yes — **120.** Date platelets ≥ 50 x 10^9/L: ☐☐ ☐☐ ☐☐ ❑ Date unknown (Month Day Year)
0 ❑ No — Go to Q. 123
8 ❑ Unknown — Go to Q. 123

121. Was a platelet count of ≥ 100 x 10^9/L achieved?

1 ❑ Yes — **122.** Date platelets ≥ 100 x 10^9/L: ☐☐ ☐☐ ☐☐ ❑ Date unknown (Month Day Year)
0 ❑ No
8 ❑ Unknown

123. Was recipient ever platelet transfusion independent?

1 ❑ Yes — **124.** Date of the last platelet transfusion:* ☐☐ ☐☐ ☐☐ ❑ Date unknown (Month Day Year)

*If recipient was platelet transfusion independent for ≥14 days but subsequently experienced a decline in platelet count and required platelet transfusions, record date of last platelet transfusion before decline in counts. If recipient has not required platelet transfusions since initial platelet recovery record date of last platelet transfusion.

0 ❑ No

Go to Q. 125 if platelet count of ≥ 20 x 10^9/L achieved; otherwise go to Q. 133

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125. After initial recovery to platelet count ≥ 20 x 10^9/L did the platelet count decline to < 20 x 10^9/L for 3 consecutive laboratory values or decline to < 20 x 10^9/L for one laboratory value and the recipient received a platelet transfusion?

1 ❑ Yes
2 ❑ No

Go to Q. 159 if platelet count of ≥100 x 10^9/L achieved, otherwise go to Q. 133

126. Date of the first day that platelet count declined below 20 x 10^9/L: ☐☐ ☐☐ ☐☐ ❑ Date unknown
Month Day Year

127. Has platelet count recovered?

1 ❑ Yes
0 ❑ No

Go to Q. 133

The following date questions relate to **subsequent** platelet recovery following a decline of platelet count to below 20 x 10^9/L. All dates should reflect no transfusions in previous 7 days, and the first of 3 consecutive laboratory values.

128. Was a platelet count of ≥ 20 x 10^9/L achieved?

1 ❑ Yes
0 ❑ No

Go to Q. 131

129. Was a platelet count of ≥ 50 x 10^9/L achieved?

1 ❑ Yes
0 ❑ No

Go to Q. 131

130. Was a platelet count of ≥ 100 x 10^9/L achieved?

1 ❑ Yes
0 ❑ No

131. Was patient ever transfusion independent following recovery from decline?

1 ❑ Yes
0 ❑ No

132. Date of the last platelet transfusion (following recovery from decline): ☐☐ ☐☐ ☐☐ ❑ Date unknown
Month Day Year

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Suspected etiology of failure to achieve a platelet count ≥ 100 x 10^9/L or decline in platelet count to < 20 x 10^9/L:

133. Persistent disease or relapse:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

134. Graft versus host disease:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

135. Non-viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

136. Immune-mediated:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Immune mediated etiology:

	Yes	No	
137.	1 ❑	0 ❑	Cellular
138.	1 ❑	0 ❑	Antibody
139.	1 ❑	0 ❑	Third party engraftment
140.	1 ❑	0 ❑	Unknown

141. Suspected viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus suspected:

	Yes	No	
142.	1 ❑	0 ❑	Cytomegalovirus (CMV)
143.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
144.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
145.	1 ❑	0 ❑	Varicella
146.	1 ❑	0 ❑	Other, specify: _____

147. Documented viral infection:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Virus involved:

	Yes	No	
148.	1 ❑	0 ❑	Cytomegalovirus (CMV)
149.	1 ❑	0 ❑	Human Herpes Virus Type 6 (HHV6)
150.	1 ❑	0 ❑	Herpes Simplex Virus (HSV)
151	1 ❑	0 ❑	Varicella
152.	1 ❑	0 ❑	Other, specify: _____

153. Drugs:
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

Therapy:

	Yes	No	
154.	1 ❑	0 ❑	Ganciclovir
155.	1 ❑	0 ❑	Bactrim, Septra, Trimethoprim-sulfamethoxazole
156.	1 ❑	0 ❑	Other, specify: _____

157. Veno-occlusive disease (VOD):
- 1 ❑ Yes
- 0 ❑ No
- 8 ❑ Unknown

158. Etiology undetermined:
- 1 ❑ Yes
- 0 ❑ No

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Erythropoiesis

159. Has patient received red blood cell (RBC) transfusions since last report?

1 ❑ Yes — **160.** Date of last RBC transfusion:* ☐☐ ☐☐ ☐☐ ❑ Date unknown
(Month Day Year)

0 ❑ No

** If patient was RBC transfusion independent for ≥1 month but subsequently experienced a decline in RBC count and required RBC transfusions, record date of last RBC transfusion before decline in counts. If patient has not required RBC transfusions since initial date of recovery, record date of last RBC transfusion.*

Current Hematologic Findings

161. Date of most recent CBC: ☐☐ ☐☐ ☐☐
(Month Day Year)

Actual CBC results:

162. WBC ☐☐☐.☐ x 10^9/L

163. Neutrophils ☐☐ %

164. Lymphocytes ☐☐ %

165. Hemoglobin ☐☐.☐ g/dL ❑ Transfused

166. Hematocrit ☐☐ % ❑ Transfused

167. Platelets ☐☐ x 10^9/L ❑ Transfused

168. Were chimerism studies performed since last report?

1 ❑ Yes — Complete following page

0 ❑ No — Go to Q. 169

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Autotransplants only

Chimerism Studies

(Provide date(s), method(s) and other information for all chimerism studies performed since date of last report)

Date			Method (See Valid List Below)	Cell Type (See Valid List Below)	Number of Cells Examined (Total Cells)	Number of Donor Cells	Number of Host Cells	Number of Unknown Origin (third party) Cells	Percent Donor Cells		Percent Host Cells		Percent Unknown Origin (third party) Cells	
Month	Day	Year							Quant.	*Non-Quant.	Quant.	*Non-Quant.	Quant.	*Non-Quant.

Valid Method Codes

(Insert number in box above to indicate method used)

1 – Standard Cytogenetics
2 – Fluorescent In situ Hybridization (FISH)
3 – Restriction Fragment-length polymorphisms (RFLP)
4 – Polymerase Chain Reaction (PCR)
5 – HLA Serotyping
6 – VNTR
7 – Other, specify: _____

Valid Cell Types

(Insert number in box above to indicate cell type used)

1 – Bone Marrow (BM)
2 – Peripheral Blood Mononuclear Cells (PBMC)
3 – T-Cells
4 – B-Cells
5 – Red Cells
6 – Monocytes
7 – Neutrophils
8 – Other, specify: _____

* If performed by non-quantitative method, indicate the presence of donor, host or third party cells by (+)

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Graft-vs-Host Disease (GVHD)

169. Was specific therapy used since last report to prevent or induce GVHD, or promote engraftment?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

Allografts: Go to Q. 186

Autografts: Go to Q. 326

For each agent listed below indicate whether or not it was used to prevent or induce GVHD since last report:

	Yes	No	
170.	1 ❑	0 ❑	Methotrexate
171.	1 ❑	0 ❑	Cyclosporine
172.	1 ❑	0 ❑	FK 506 (Tacrolimus)
173.	1 ❑	0 ❑	Corticosteroids
174.	1 ❑	0 ❑	ALS, ALG, ATS, ATG
175.	1 ❑	0 ❑	Azathioprine
176.	1 ❑	0 ❑	Cyclophosphamide
177.	1 ❑	0 ❑	In vivo anti T-lymphocyte monoclonal antibody:
183.	1 ❑	0 ❑	In vivo immunotoxin, specify: _____
184.	1 ❑	0 ❑	Blinded randomized trial; specify agent being studied: _____
185.	1 ❑	0 ❑	Other, specify: _____

	Yes	No	
178.	1 ❑	0 ❑	Anti IL-2
179.	1 ❑	0 ❑	Anti CD 25
180.	1 ❑	0 ❑	Campath
181.	1 ❑	0 ❑	OKT3
182.	1 ❑	0 ❑	Other, specify: _____

186. Was acute GVHD present at time of last report?

1 ❑ Yes — Go to Q. 195
0 ❑ No

187. Did acute GVHD develop since date of last report?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

Go to Q. 238

188. Date of onset: ☐☐ ☐☐ ☐☐ (Month Day Year)

What was diagnosis based on?

189. Histologic evidence:

1 ❑ Yes
0 ❑ No

Sites:

	Yes	No	
190.	1 ❑	0 ❑	Skin
191.	1 ❑	0 ❑	Gut
192.	1 ❑	0 ❑	Liver
193.	1 ❑	0 ❑	Other, specify: _____

194. Clinical evidence:

1 ❑ Yes
0 ❑ No

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195. Maximum overall grade since last report: 1 ☐ I 2 ☐ II 3 ☐ III 4 ☐ IV

List the maximum severity of organ involvement attributed to acute GVHD:

	Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
196. Skin:	1 ☐ No rash	2 ☐ Maculopapular rash, <25% of body surface	3 ☐ Maculopapular rash, 25–50% of body surface	4 ☐ Generalized erythroderma	5 ☐ Generalized erythroderma with bullae formation and desquamation
197. Intestinal tract (use ml/day for adult patients and ml/m²/day for pediatric patients):	0 ☐ No diarrhea 1 ☐ Diarrhea ≤500 ml/day or <280 ml/m²/day	2 ☐ Diarrhea >500 but ≤1000 ml/day or 280–555 ml/m²/day	3 ☐ Diarrhea >1000 but ≤1500 ml/day or 556–833 ml/m²/day	4 ☐ Diarrhea >1500 ml/day or >833 ml/m²/day	5 ☐ Severe abdominal pain, with or without ileus
198. Liver:	1 ☐ Bilirubin <2.0 mg/dL	2 ☐ Bilirubin 2.0–3.0 mg/dL	3 ☐ Bilirubin 3.1–6.0 mg/dL	4 ☐ Bilirubin 6.1–15.0 mg/dL	5 ☐ Bilirubin >15.0 mg/dL

199. Other organ involvement?

1 ☐ Yes
0 ☐ No

	Yes	No	
200.	1 ☐	0 ☐	Upper GI tract
201.	1 ☐	0 ☐	Lung
202.	1 ☐	0 ☐	Other, specify: _____

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203. Was specific therapy used to **treat** acute GVHD since last report? 1 ☐ Yes 0 ☐ No

For each agent listed below indicate whether or not it was used to **treat** acute GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking? Yes	Still taking? No
204. Methotrexate	0 ☐	1 ☐	2 ☐	3 ☐	**205.** 1 ☐	0 ☐
206. Cyclosporine	0 ☐	1 ☐	2 ☐	3 ☐	**207.** 1 ☐	0 ☐
208. FK 506 (Tacrolimus)	0 ☐	1 ☐	2 ☐	3 ☐	**209.** 1 ☐	0 ☐
210. Systemic Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**211.** 1 ☐	0 ☐
212. Topical Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**213.** 1 ☐	0 ☐
214. ALS, ALG, ATS, ATG	0 ☐	1 ☐	2 ☐	3 ☐	**215.** 1 ☐	0 ☐
216. Azathioprine	0 ☐	1 ☐	2 ☐	3 ☐	**217.** 1 ☐	0 ☐
218. Cyclo-phosphamide	0 ☐	1 ☐	2 ☐	3 ☐	**219.** 1 ☐	0 ☐
220. Thalidomide	0 ☐	1 ☐	2 ☐	3 ☐	**221.** 1 ☐	0 ☐
In vivo anti-T-lymphocyte monoclonal antibody:						
222. Anti IL-2	0 ☐	1 ☐	2 ☐	3 ☐	**223.** 1 ☐	0 ☐
224. Anti CD 25	0 ☐	1 ☐	2 ☐	3 ☐	**225.** 1 ☐	0 ☐
226. Campath	0 ☐	1 ☐	2 ☐	3 ☐	**227.** 1 ☐	0 ☐
228. OKT3	0 ☐	1 ☐	2 ☐	3 ☐	**229.** 1 ☐	0 ☐
230. Other, antibody specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**231.** 1 ☐	0 ☐
232. In vivo immunotoxin, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**233.** 1 ☐	0 ☐
234. Blinded randomized trial; specify agent(s) being studied: _____	0 ☐	1 ☐	2 ☐	3 ☐	**235.** 1 ☐	0 ☐
236. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**237.** 1 ☐	0 ☐

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238. Was chronic GVHD present at time of last report?

1 ❑ Yes
0 ❑ No

239. Chronic GVHD is still present or was present at time of death:

1 ❑ Yes — Go to Q. 256
0 ❑ No

240. Did clinical chronic GVHD develop since date of last report?

1 ❑ Yes
0 ❑ No — Go to Q. 326
8 ❑ Unknown — Go to Q. 326

241. Date of onset: ☐☐ ☐☐ ☐☐ (Month Day Year)

242. Progressed from acute GVHD?

1 ❑ Yes
0 ❑ No

243. Karnofsky/Lansky score (see page 1) at diagnosis of chronic GVHD: ☐☐☐

244. Platelet count at diagnosis of chronic GVHD: ☐☐☐☐.☐ x 10^9/L

245. Total serum bilirubin at diagnosis of chronic GVHD: ☐☐.☐

Unit of measurement for bilirubin:

1 ❑ mg/dL
2 ❑ μmol/L

What was diagnosis based on?

246. Histologic evidence:

1 ❑ Yes
0 ❑ No

255. Clinical evidence:

1 ❑ Yes
0 ❑ No

Sites:

	Yes	No	
247.	1 ❑	0 ❑	Skin
248.	1 ❑	0 ❑	Gut
249.	1 ❑	0 ❑	Liver
250.	1 ❑	0 ❑	Buccal mucosa/lip
251.	1 ❑	0 ❑	Conjunctiva
252.	1 ❑	0 ❑	Lung
253.	1 ❑	0 ❑	Muscle
254.	1 ❑	0 ❑	Other, specify: _____

Continued on next page

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256. Maximum grade of chronic GVHD:

1 ☐ Limited (*Localized skin involvement and/or hepatic dysfunction due to chronic GVHD*)

2 ☐ Extensive *(Generalized skin involvement; or localized skin involvement and/or hepatic dysfunction due to chronic GVHD, plus :*
-Liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,
-Involvement of eye: Schirmer's test with < 5 mm wetting; or,
-Involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or,
-Involvement of any other target organ)

257. Overall severity: 1 ☐ Mild 2 ☐ Moderate 3 ☐ Severe

Indicate organ involvement with chronic GVHD from list below:

		Yes	No	
Skin/Hair:	**258.**	1 ☐	0 ☐	Subclinical (biopsy findings only)
	259.	1 ☐	0 ☐	Rash
	260.	1 ☐	0 ☐	Scleroderma
	261.	1 ☐	0 ☐	Dyspigmentation
	262.	1 ☐	0 ☐	Contractures
	263.	1 ☐	0 ☐	Alopecia
	264.	1 ☐	0 ☐	Other skin/hair involvement, specify: _____
Eyes:	**265.**	1 ☐	0 ☐	Dry eyes
	266.	1 ☐	0 ☐	Corneal erosion/conjunctivitis
	267.	1 ☐	0 ☐	Other eye involvement, specify: _____
Mouth:	**268.**	1 ☐	0 ☐	Lichenoid changes
	269.	1 ☐	0 ☐	Mucositis/ulcers
	270.	1 ☐	0 ☐	Other mouth involvement, specify: _____
Lung:	**271.**	1 ☐	0 ☐	Bronchiolitis obliterans
	272.	1 ☐	0 ☐	Other lung involvement, specify: _____
GI Tract:	**273.**	1 ☐	0 ☐	Esophageal involvement
	274.	1 ☐	0 ☐	Chronic nausea/vomiting
	275.	1 ☐	0 ☐	Chronic diarrhea
	276.	1 ☐	0 ☐	Malabsorption
	277.	1 ☐	0 ☐	Other GI tract involvement, specify: _____
Liver:	**278.**	1 ☐	0 ☐	Liver involvement, specify: _____
GU Tract:	**279.**	1 ☐	0 ☐	Vaginitis/stricture
	280.	1 ☐	0 ☐	Other GU involvement, specify: _____
Musculoskeletal:	**281.**	1 ☐	0 ☐	Arthritis
	282.	1 ☐	0 ☐	Myositis
	283.	1 ☐	0 ☐	Myasthenia
	284.	1 ☐	0 ☐	Other musculoskeletal involvement, specify: _____
Hematologic:	**285.**	1 ☐	0 ☐	Thrombocytopenia
	286.	1 ☐	0 ☐	Eosinophilia
	287.	1 ☐	0 ☐	Autoantibodies
	288.	1 ☐	0 ☐	Other hematologic involvement, specify: _____
Other:	**289.**	1 ☐	0 ☐	Specify: _____

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290. Was specific therapy used to **treat** chronic GVHD since last report? 1 ☐ Yes 0 ☐ No — Go to Q. 325

For each agent listed below indicate whether or not it was used to **treat** chronic GVHD

	No, drug not given	Drug continued at prophylactic dose	Yes, drug started	Yes, dose increased	Still taking? Yes	Still taking? No
291. ALS, ALG, ATS, ATG	0 ☐	1 ☐	2 ☐	3 ☐	**292.** 1 ☐	0 ☐
293. Azathioprine	0 ☐	1 ☐	2 ☐	3 ☐	**294.** 1 ☐	0 ☐
295. Cyclosporine	0 ☐	1 ☐	2 ☐	3 ☐	**296.** 1 ☐	0 ☐
297. FK 506 (Tacrolimus)	0 ☐	1 ☐	2 ☐	3 ☐	**298.** 1 ☐	0 ☐
299. Systemic Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**300.** 1 ☐	0 ☐
301. Topical Corticosteroids	0 ☐	1 ☐	2 ☐	3 ☐	**302.** 1 ☐	0 ☐
303. Cyclo-phosphamide	0 ☐	1 ☐	2 ☐	3 ☐	**304.** 1 ☐	0 ☐
305. Thalidomide	0 ☐	1 ☐	2 ☐	3 ☐	**306.** 1 ☐	0 ☐
In vivo anti-T-lymphocyte monoclonal antibody						
307. Anti IL-2	0 ☐	1 ☐	2 ☐	3 ☐	**308.** 1 ☐	0 ☐
309. Anti CD 25	0 ☐	1 ☐	2 ☐	3 ☐	**310.** 1 ☐	0 ☐
311. Campath	0 ☐	1 ☐	2 ☐	3 ☐	**312.** 1 ☐	0 ☐
313. OKT3	0 ☐	1 ☐	2 ☐	3 ☐	**314.** 1 ☐	0 ☐
315. Other, antibody specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**316.** 1 ☐	0 ☐
317. In vivo immunotoxin, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**318.** 1 ☐	0 ☐
319. Blinded randomized trial; specify agent(s) being studied: _____	0 ☐	1 ☐	2 ☐	3 ☐	**320.** 1 ☐	0 ☐
321. Other, specify: _____	0 ☐	1 ☐	2 ☐	3 ☐	**322.** 1 ☐	0 ☐

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

323. Is patient still receiving treatment for chronic GVHD?

1 ❑ Yes

0 ❑ No —— **324.** Date last treatment was administered: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

325. Is chronic GVHD still present?

1 ❑ Yes

0 ❑ No

8 ❑ No symptoms, but patient still receiving treatment

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326. Did patient develop clinically significant infection since date of last report? 1 ❑ Yes 0 ❑ No

Select site and organism from lists shown on the next page and place number in the appropriate spaces. If more than one site or organism was involved, list one site of infection and organism on the first line; second site and/or organism on second line.

			Site	Organism	Date of Onset: Month	Day	Year	Did infection resolve? Yes	No
327. ❑ Bacterial									
Typical	First	**328.**		**329.** _____	**330.**			**331.** 1 ❑	0 ❑
	Second	**332.**		**333.** _____	**334.**			**335.** 1 ❑	0 ❑
		336. Other bacterium, specify: _____							
Atypical	First	**337.**		**338.** B	**339.**			**340.** 1 ❑	0 ❑
	Second	**341.**		**342.** B	**343.**			**344.** 1 ❑	0 ❑
		345. Other atypical bacterium, specify: _____							
346. ❑ Fungal									
	First	**347.**		**348.** F	**349.**			**350.** 1 ❑	0 ❑
	Second	**351.**		**352.** F	**353.**			**354.** 1 ❑	0 ❑
		355. Other fungus, specify: _____							
356. ❑ Viral									
	First	**357.**		**358.** V	**359.**			**360.** 1 ❑	0 ❑
	Second	**361.**		**362.** V	**363.**			**364.** 1 ❑	0 ❑
		365. Other virus, specify: _____							
366. ❑ Parasitic									
	First	**367.**		**368.** P	**369.**			**370.** 1 ❑	0 ❑
	Second	**371.**		**372.** P	**373.**			**374.** 1 ❑	0 ❑
		375. Other parasite, specify: _____							
376. ❑ No organism identified									
	First	**377.**		**378.** O509	**379.**			**380.** 1 ❑	0 ❑
	Second	**381.**		**382.** O509	**383.**			**384.** 1 ❑	0 ❑

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Codes for Common Sites of Infection

01 Blood/buffy coat
02 Disseminated – generalized, isolated at 3 or more distinct sites
03 *Central Nervous System unspecified*
04 Brain
05 Spinal cord
06 Meninges and CSF
10 *Gastrointestinal Tract unspecified*
11 Lips
12 Tongue, oral cavity and oro-pharynx
13 Esophagus
14 Stomach
15 Gallbladder and biliary tree (not hepatitis), pancreas
16 Small intestine
17 Large intestine
18 Feces/stool
19 Peritoneum
20 Liver
30 *Respiratory unspecified*
31 Upper airway and nasopharynx
32 Laryngitis/larynx
33 Lower respiratory tract (lung)
34 Pleural cavity, pleural fluid
35 Sinuses
40 *Genito-Urinary Tract unspecified*
41 Kidneys, renal pelvis, ureters and bladder
42 Prostate
43 Testes
44 Fallopian tubes, uterus, cervix
45 Vagina
50 *Skin unspecified*
51 Genital area
52 Cellulitis
53 Herpes Zoster
54 Rash, pustules or abscesses not typical of any of the above
60 Central venous catheter, not otherwise specified
61 Catheter insertion site
62 Catheter tip
70 Eyes
75 Ear
80 *Other unspecified*
81 Joints
82 Bone marrow
83 Bone cortex (osteomyelitis)
84 Muscle (excluding cardiac)
85 Cardiac (endocardium, myocardium, pericardium)
86 Lymph nodes
87 Spleen

Codes for Commonly Reported Organisms

1. Bacteria

(Indicate code for atypical bacteria; list bacterium for non-atypical bacteria.)

100 Atypical bacteria, not otherwise specified
101 Coxiella
102 Legionella
103 Leptospira
104 Listeria
105 Mycoplasma
106 Nocardia
107 Rickettsia
110 Tuberculosis, NOS (AFB, acid fast bacillus, Koch bacillus)
111 Typical tuberculosis (TB, Tuberculosis)
112 Mycobacteria (avium, bovium, intracellulare)
113 Chlamydia
119 Atypical bacteria – other, specify

2. Fungal Infections

200 Candida, not otherwise specified
201 Candida albicans
202 Candida krusei
203 Candida parapsilosis
204 Candida tropicalis
205 Torulopsis glabrata (a subspecies of candida)
209 Candida, other
210 Aspergillus, not otherwise specified
211 Aspergillus flavus
212 Aspergillus fumigatus
213 Aspergillus niger
219 Aspergillus, other
220 Cryptococcus species
230 Fusarium species
240 Mucormycosis (zygomycetes, rhizopus)
250 Yeast, not otherwise specified
259 Other fungus, specify

3. Viral Infections

301 Herpes Simplex (HSV1, HSV2)
302 Herpes Zoster (Chicken pox, Varicella)
303 Cytomegalovirus (CMV)
304 Adenovirus
305 Enterovirus (Coxsackie, Echo, Polio)
306 Hepatitis A (HAV)
307 Hepatitis B (HBV, Australian antigen)
308 Hepatitis C (HCV)
309 HIV-1 (HTLV-III)
310 Influenza
311 Measles (Rubeola)
312 Mumps
313 Papovavirus
314 Respiratory syncytial virus (RSV)
315 Rubella (German Measles)
316 Parainfluenza
317 Human herpesvirus-6 (HHV-6)
318 Epstein-Barr virus (EBV)
319 Polyomavirus
320 Rotavirus
321 Rhinovirus
329 Other Viral, specify

4. Parasite Infections

401 Pneumocystis (PCP)
402 Toxoplasma
403 Giardia
404 Cryptosporidium
409 Other parasite (amebiasis, echinococcal cyst, trichomonas – either vaginal or gingivitis), specify

5. Other Infections

509 No organism identified

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Pulmonary function

385. Has patient developed interstitial pneumonitis (IPn) since date of last report?

Interstitial pneumonitis is characterized by hypoxia and diffuse interstitial infiltrates on chest x-ray not caused by fluid overload.

1 ❑ Yes
0 ❑ No

386. How many episodes of IPn occurred since date of last report? ☐

Note: If more than one episode of IPn, photocopy this page and complete Q. 385 – 406 for subsequent episode(s).

387. Date of onset of IPn: ☐☐ ☐☐ ☐☐
Month Day Year

388. Were diagnostic tests other than radiographic studies done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
389.	1 ❑	0 ❑	Bronchoalveolar lavage
390.	1 ❑	0 ❑	Transbronchial biopsy
391.	1 ❑	0 ❑	Open lung biopsy
392.	1 ❑	0 ❑	Autopsy
393.	1 ❑	0 ❑	Other, specify: _____

394. Was an organism isolated?

1 ❑ Yes
0 ❑ No (idiopathic, or no organism isolated)

Etiology:

	Yes	No	
395.	1 ❑	0 ❑	Pneumocystis carinii
396.	1 ❑	0 ❑	Aspergillus
397.	1 ❑	0 ❑	Candida
398.	1 ❑	0 ❑	Toxoplasma
399.	1 ❑	0 ❑	Respiratory syncytial virus
400.	1 ❑	0 ❑	Cytomegalovirus
401.	1 ❑	0 ❑	Herpes simplex
402.	1 ❑	0 ❑	Adenovirus
403.	1 ❑	0 ❑	Human herpes virus 6
404.	1 ❑	0 ❑	Other virus, specify: _____
405.	1 ❑	0 ❑	Other, specify: _____

406. Has interstitial pneumonitis resolved?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

407. Did patient develop pulmonary abnormalities other than interstitial pneumonitis since date of last report?

1 ❑ Yes
0 ❑ No

408. Did patient develop Acute Respiratory Distress Syndrome (ARDS) since last report?

1 ❑ Yes
0 ❑ No

409. Date of onset of ARDS: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

410. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
411.	1 ❑	0 ❑	Bronchoalveolar lavage
412.	1 ❑	0 ❑	Transbronchial biopsy
413.	1 ❑	0 ❑	Open lung biopsy
414.	1 ❑	0 ❑	Autopsy
415.	1 ❑	0 ❑	Other, specify: _____

416. Did patient develop bronchiolitis obliterans since last report?

1 ❑ Yes
0 ❑ No

417. Date of onset: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

418. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
419.	1 ❑	0 ❑	Bronchoalveolar lavage
420.	1 ❑	0 ❑	Transbronchial biopsy
421.	1 ❑	0 ❑	Open lung biopsy
422.	1 ❑	0 ❑	Autopsy
423.	1 ❑	0 ❑	Other, specify: _____

424. Did patient develop pulmonary hemorrhage since last report?

1 ❑ Yes
0 ❑ No

425. Date of onset: [ ][ ] [ ][ ] [ ][ ]
Month Day Year

426. Were diagnostic tests done?

1 ❑ Yes
0 ❑ No

Diagnosis was evaluated by:

	Yes	No	
427.	1 ❑	0 ❑	Bronchoalveolar lavage
428.	1 ❑	0 ❑	Transbronchial biopsy
429.	1 ❑	0 ❑	Open lung biopsy
430.	1 ❑	0 ❑	Autopsy
431.	1 ❑	0 ❑	Other, specify: _____

432. Did patient develop other non-infectious pulmonary abnormalities since last report?

1 ❑ Yes
0 ❑ No

433. Specify: _____

TEAM [ ][ ][ ][ ] IUBMID [ ][ ][ ][ ][ ][ ]

Liver function

434. Did patient develop non-infectious liver toxicity since last report?

1 ❑ Yes
0 ❑ No

435. What was the date of onset? [ ][ ] Month [ ][ ] Day [ ][ ] Year

Etiology:

	Yes	No	
436.	1 ❑	0 ❑	Veno-occlusive disease
437.	1 ❑	0 ❑	Other, specify: _____
438.	1 ❑	0 ❑	Unknown

439. Has liver toxicity resolved?

1 ❑ Yes
0 ❑ No
8 ❑ Unknown

440. Did patient develop any other non-infectious clinically significant organ impairment or disorder since last report?

1 ❑ Yes
0 ❑ No

	Yes	No	
441.	1 ❑	0 ❑	Renal failure requiring dialysis
442.	1 ❑	0 ❑	TTP/HUS or similar syndrome
443.	1 ❑	0 ❑	Hemorrhage, specify site:
444.	1 ❑	0 ❑	CNS
445.	1 ❑	0 ❑	Upper GI tract
446.	1 ❑	0 ❑	Lower GI tract
447.	1 ❑	0 ❑	Other, specify: _____
448.	1 ❑	0 ❑	Hemorrhagic cystitis
449.	1 ❑	0 ❑	Seizures
450.	1 ❑	0 ❑	Cataracts
451.	1 ❑	0 ❑	Avascular necrosis
452.	1 ❑	0 ❑	Hypothyroidism
453.	1 ❑	0 ❑	Gonadal dysfunction
454.	1 ❑	0 ❑	Growth hormone deficiency/growth disturbance
455.	1 ❑	0 ❑	Other, specify: _____

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

456. Did a new malignancy, lymphoproliferative or myeloproliferative disorder appear since last report? *(If more than one new malignancy developed, copy this page and complete for each new cancer)*

1 ❑ Yes
0 ❑ No

457. Date of diagnosis: ☐☐ ☐☐ ☐☐ (Month Day Year)

458. Origin of cells:
1 ❑ Host
2 ❑ Donor
8 ❑ Unknown
7 ❑ Not tested

Diagnosis (***send copy of pathology report/other documentation***):

	Yes	No	
459.	1 ❑	0 ❑	Clonal cytogenetic abnormality without leukemia or MDS
460.	1 ❑	0 ❑	Acute myeloid leukemia
461.	1 ❑	0 ❑	Other leukemia, specify: _____
462.	1 ❑	0 ❑	Myelodysplasia
463.	1 ❑	0 ❑	Lymphoma or lymphoproliferative disease

464. EBV positive? 1 ❑ Yes 0 ❑ No 8 ❑ Unknown

465.	1 ❑	0 ❑	Hodgkin disease
466.	1 ❑	0 ❑	Other cancer

467. Primary site: _____

468. Histologic type: _____

469. Behavior:
1 ❑ Benign
2 ❑ In situ
3 ❑ Malignant/invasive
8 ❑ Unknown

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

Death Information

470. Date of death: ☐☐ ☐☐ ☐☐
Month Day Year

Cause(s) of death:

Enter appropriate cause of death below. If a code number for "Other, specify" is entered, write the cause in the space provided.

471. Primary: ☐☐☐ Specify: _____

Contributing or secondary causes:

472. ☐☐☐ Specify: _____

473. ☐☐☐ Specify: _____

474. ☐☐☐ Specify: _____

475. ☐☐☐ Specify: _____

476. ☐☐☐ Specify: _____

Cause of Death Codes

10 Graft rejection or failure

20 Infection (other than interstitial pneumonia)
- 21 Bacterial
- 22 Fungal
- 23 Viral
- 24 Protozoal
- 25 Infection, organism not identified
- 29 Other infection, specify

30 Interstitial pneumonia
- 31 Viral, CMV
- 32 Viral, other
- 33 Pneumocystis
- 34 Fungus
- 39 Other IPn, specify

40 Adult Respiratory Distress Syndrome

50 Acute GVHD
60 Chronic GVHD

70 Recurrence or persistence of primary disease

NOTE: Code "70" may only be used as a primary cause of death, not a contributing or secondary cause.

80 Organ failure (not due to GVHD or infection)
- 81 Liver
- 82 VOD
- 83 Cardiac (Cardiomyopathy)
- 84 Pulmonary
- 85 CNS
- 86 Renal
- 89 Other organ failure, specify

90 Secondary malignancy

100 Hemorrhage

110 Accidental death

900 Other, specify

477. Was cause of death confirmed by autopsy?

1 ☐ Yes — ***Send copy of autopsy report when available***
0 ☐ No
8 ☐ Unknown
6 ☐ Pending

FOLLOW-UP INSTITUTIONAL INFORMATION

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

FOR REGISTRY USE ONLY:

I.D. ☐–☐☐☐☐–☐☐☐☐☐☐

Date received:

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ ☐☐ ☐☐ Month Day Year

Date of report: ☐☐ ☐☐ ☐☐ Month Day Year

---

1. Signed: _____ /

Person completing this form / Please print name

2. Date last report completed: ☐☐ ☐☐ ☐☐ Month Day Year

3. Name of doctor for correspondence: _____

Institution: _____

Telephone: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Extension: ☐☐☐☐☐

Fax: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

4. Make reimbursement check payable to: _____

5. Patient or authorized family member/guardian is aware of, and has consented to, the fact that this case is being entered into the Registry database:

_____(physician's initials).

FOLLOW-UP: INSERT VIII
Breast Cancer

FOR REGISTRY USE ONLY:

I.D. ☐ – ☐☐☐☐ – ☐☐☐☐☐☐

Date received:

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

(Institutional Unique Blood or Marrow Transplant Identification Number)

Registry: IBMTR ABMTR (circle one)

Date of transplant for which this form is being completed: ☐☐ Month ☐☐ Day ☐☐ Year

Date of report: ☐☐ Month ☐☐ Day ☐☐ Year

Follow-up Information

* ***Report data for date of last contact as reported in Q.3 of Follow-up Core Form or immediately prior to death.***

1. Was planned post transplant treatment (treatment before progressive disease) given since date of last report?

1 ☐ Yes
0 ☐ No → *Go to Q.9*

2. Was disease restaged prior to planned posttransplant treatment?

1 ☐ Yes
0 ☐ No

Specify treatment given whether restaged or not:

	Yes	No	
3.	1 ☐	0 ☐	Chemotherapy, specify: _____
4.	1 ☐	0 ☐	Hormone therapy, specify: _____
5.	1 ☐	0 ☐	Radiation therapy, specify: _____
6.	1 ☐	0 ☐	Immune therapy, specify: _____
7.	1 ☐	0 ☐	Other, specify: _____

8. Specify best response to transplant including planned posttransplant treatment:

1 ☐ Complete response (*complete disappearance of all known disease for ≥ 4 weeks*)
2 ☐ Complete response with persistent bone scan or x-ray abnormalities of unknown significance
3 ☐ Partial response (*≥ 50% reduction in greatest diameter of all sites of known disease and no new sites of disease for ≥ 4 weeks*)
4 ☐ No response: < 50% reduction in greatest diameter of all sites of known disease and no new sites of disease
5 ☐ Progressive disease: increase in size of sites of known disease or new sites of disease
Specify site(s) of persistent/new disease: _____
6 ☐ Not evaluable, toxic death
7 ☐ Not evaluable, other reason, specify: _____

TEAM ☐☐☐☐ IUBMID ☐☐☐☐☐☐

9. Most recent status of breast cancer: (*for patients who died, report status at time of death*)

1 ☐ Free of breast cancer; no recurrence posttransplant

2 ☐ Free of breast cancer except for persistent scan abnormalities of unknown significance, no recurrence posttransplant

3 ☐ Persistent breast cancer without progression (*never achieved CR or PR*)

4 ☐ Progressive disease (*never achieved CR or PR*)

Date of progression ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

5 ☐ Recurrent disease (relapse after complete remission)

Date of progression ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

6 ☐ Free of breast cancer after posttransplant recurrence

Date of recurrence ☐☐ ☐☐ ☐☐ Site(s): _____
Month Day Year

7 ☐ Not evaluable; explain: _____

10. Date current status established ☐☐ ☐☐ ☐☐
Month Day Year

First site(s) of progression/recurrence:

	Yes	No	
11.	1 ☐	0 ☐	Lymph node
12.	1 ☐	0 ☐	Bone marrow
13.	1 ☐	0 ☐	CNS
14.	1 ☐	0 ☐	Liver
15.	1 ☐	0 ☐	Lung
15.2	1 ☐	0 ☐	Local (chest wall)
15.3	1 ☐	0 ☐	Contralateral breast
16.	1 ☐	0 ☐	Other, specify:_____

IBMTR

International Bone Marrow Transplant Registry

Working Committee Meetings & Data Management Workshops

ABMTR North America

Autologous Blood & Marrow Transplant Registry

Keystone Resort, Colorado

January 13-15,1996

immediately preceding the
Keystone Symposium on "Blood Cell & Bone Marrow Transplants"
Keystone, January 15-21, 1996

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IBMTR

Working Committee Meetings & Data Management Workshops

ABMTR

January 13-15, 1996 * Keystone, Colorado

Program Goals & Objectives

- The 1996 joint meeting of the IBMTR and ABMTR will be held in Keystone, Colorado immediately preceding the Keystone Symposium on "Blood Cell & Bone Marrow Transplants". Participants may take advantage of the opportunity to attend both meetings, efficiently utilizing valuable travel funds.

- **All participating IBMTR and ABMTR team members are encouraged to attend.** We hope to have all contributing teams represented at this year's Meeting.

- Current data on use and outcome of blood and bone marrow transplants will be presented.

- All participants are invited to attend and contribute to meetings of IBMTR and ABMTR Working Committees in their areas of interest and expertise. Committees will discuss Registry analyses currently in progress and directions for future research. See Registration Form and Agenda for Committee listings.

- Data Managers and Research Nurses are encouraged to attend interactive Data Management Workshops. The newly revised IBMTR/ABMTR Reporting Forms, designed in collaboration with the US National Marrow Donor Program (NMDP), will be reviewed in detail. StemCell Technologies, Inc. will demonstrate StemSoft software for the newly revised IBMTR/ABMTR Forms and an interrelated statistical analysis package. IBMTR/ABMTR Registration Procedures will be reviewed.

- Approaches to use and analysis of clinical transplant data will be presented.

Participants Will Benefit From Attending by:

- Participating in discussions of current and future IBMTR and ABMTR analyses, learning the advantages and limitations of using Registry data to address issues in transplantation

- Participating in Plenary Sessions addressing important scientific issues in blood and marrow transplantation

- Lending expertise to IBMTR and ABMTR Working Committees

- Meeting and interacting with Statistical Center staff

- Obtaining up-to-date statistics of IBMTR and ABMTR data.

IBMTR & ABMTR

Working Committee Meetings & Data Management Workshops

January 13-15, 1996 * Keystone, Colorado

Scientific Program

The IBMTR/ABMTR Meeting will provide a forum for members to discuss current blood and marrow research activities and plan future studies that address critical and timely issues in transplantation.

IBMTR & ABMTR Working Committees

Working Committees allow involvement of all participating centers in IBMTR and ABMTR studies. All teams are invited to send one or more representatives to participate. Senior and junior faculty members are encouraged to register for Committees in specific areas of interest and/or expertise.

IBMTR

- Acute Leukemia
- Chronic Myelogenous Leukemia
- CLL/Lymphoma/Multiple Myeloma
- Long-term Complications/Second Cancers
- GVHD/GVL/Immune Reconstitution
- Aplastic Anemia/Fanconi Anemia
- Metabolic Disease/Immune Deficiencies
- Histocompatibility/Alternative Donors & Stem Cell Sources

ABMTR

- Leukemia
- Lymphoma
- Breast Cancer
- Multiple Myeloma
- Pediatric Cancers

Data Management Workshops

Data managers and research nurses will find topics of interest and direct communication with on-site Statistical Staff members leading informal participatory workshops on two tracks.

- **Track I** features fundamental concepts for IBMTR/ABMTR data managers attending the Data Management Workshops for the first time.
- **Track II** designed for more experienced data management and nursing professionals, features special topics related to clinical research.

Both tracks will provide discussion of the many recent changes in IBMTR/ABMTR Registration and Reporting procedures. Additionally, StemCell Technologies, Inc., will demonstrate their StemSoft software for the newly revised IBMTR/ABMTR Forms and their interrelated statistical analysis package.

"Hands-on" training with StemSoft is available on Sunday, January 14th for those who preregister with StemCell Technologies, Inc.

More About IBMTR/ABMTR Data Management Workshops

IBMTR/ABMTR Data Management Workshops, primarily designed for Data Managers and Nurses, are conducted in an informal setting, and provide for open discussion between Statistical Center staff and meeting participants. The program includes brief overview presentations by Statistical Center personnel and others followed by roundtable discussions among members of collaborating bone marrow transplant centers. This series of Data Management Workshops will feature an emphasis on issues related to allo- and autotransplants for leukemia, lymphoma and breast cancer. Key Statistical Center staff members will be on hand to answer your questions:

Mary M. Horowitz, MD, MS, Scientific Director
John P. Klein, PhD, Statistical Director
Philip A. Rowlings, MD, Associate Scientific Director
Kathleen A. Sobocinski, Associate Statistical Director
Jakob Passweg, MD, Research/Clinical Fellow
D'Etta Waldoch Koser, Associate Director-International Programs
Barbara A. McGary, Information Systems Manager
Sharon K. Nell, Senior Communications Coordinator
Diane J. Knutson, Systems Coordinator

NOTE: Data Managers with questions requiring individual training sessions may contact Diane J. Knutson at 414/ 456-8325 at the Statistical Center for an appointment. Diane will be available at Keystone after the Data Management Workshops from Sunday, January 14 through Tuesday, January 16, 1996.

Hands-on Training: IBMTR/ABMTR Data Management with StemSoft

Mr. Gerry Racine from StemCell Technologies, Inc., will lead participants through this informative seminar and provide valuable advice for using StemSoft data entry software for completing the newly revised IBMTR/ABMTR registration and reporting forms, and their statistical analysis package.

The Statistical Center has worked closely with StemCell Technologies, Inc. in software development. Programs are currently available in WINDOWS (IBM-compatible) format. Workshop participants will be provided with an IBM-compatible PC during hands-on training.

Due to the technical nature of this full-day seminar, it is necessary to preregister. Please contact Violet Molnar at StemCell Technologies, Inc. in Vancouver, BC by telephone at: 604/ 877-0713 or by fax: 604/ 877-0704, to register for the Sunday seminar.

Saturday, January 13 — IBMTR/ABMTR Data Management Workshops

Track I: Fundamentals of Data Management
Track II: Special Topics Related to Clinical Research

	TRACK I	TRACK II
9:30 - 11:00AM	***Workshop I-A***	***Workshop II-A***
	Orientation/ Overview - Barbara McGary **Tips for Completing Registration Forms** - Sharon Nell **Tips for Completing Reporting Forms** - Diane Knutson	**StemSoft: Introductory Demonstration** - Gerry Racine **Retrieving Your Data** - Barbara McGary
11:15 - 12:45PM	***Workshop I-B***	***Workshop II-B***
	StemSoft Introductory Demonstration - Gerry Racine **Retrieving Your Data** - Barbara McGary	**The Evolution of BMT** - Betsy Stein, Clinical Research Manager Marrow Transplant Program Baylor University Medical Center Dallas, TX Roundtable discussions to follow
12:45 - 2:30PM	***Lunch Break***	
2:45 - 4:00PM	***Workshop I-C***	***Workshop II-C***
	Hands-on Case Completion I (Core & Graft Inserts) **Hands-on Case Completion II** (Disease-specific Inserts) - Diane Knutson - Claudia Kabler-Babbitt Clinical Studies Coordinator BMT Program Medical College of Wisconsin Milwaukee, WI	**What Do We Do With All Those Data?** (Introductory Statistics) -Kathleen A Sobocinski Roundtable discussions to follow

Sunday, January 14 — StemCell Technologies, Inc. Hands-on Training

9:00 - 5:30PM — ***IBMTR/ABMTR Data Management using updated StemSoft software****

* *requires preregistration*

Sunday, January 14 Working Committees & Plenary Session

TENTATIVE PROGRAM

8:00AM	*Registration/Information Desk*	*Foyer*
9:00 -10:15AM	*Simultaneous Working Committee Meetings*	
	IBMTR - Acute Leukemia Chair: Daniel Weisdorf Statistician: Mei-Jie Zhang	
	IBMTR - Long-term Complications/Second Cancers Chair: Gérard Socié Statistician: Kathleen A Sobocinski	
10:15 -10:40AM	*Coffee Break & Exhibits*	*Exhibit Area*
10:40 -12:00N	*Simultaneous Working Committee Meetings*	
	ABMTR - Pediatric Cancers Chair: Bruce Camitta Statistician: Corey Pelz	
	IBMTR - GVHD/GVL, Immune Reconstitution Chair: A John Barrett Statistician: John P Klein	
12:00 - 4:30PM	*Afternoon Recreation Break*	
12:00 - 2:00PM	**IBMTR Executive Committee**	*Star Slide Boardroom*
4:00PM-	*Reception - Pasta Buffet & Beverages*	*Exhibit Area*
4:30 - 6:30PM	*Scientific Plenary Sessions*	
	"Introduction" Mary M Horowitz	
	"ABMTR Update" James O Armitage	
	"IBMTR Update" Robert Peter Gale	
	"Recent Studies" Study Chairs	
	• Autotransplants for Breast Cancer	
	• Allotransplants -vs- Autotransplants for AML	
	• Purging in Autotransplants for AML	
	• The Role of Laminar Air Flow/HEPA Filtration in Allogeneic BMT	
	KEYNOTE SPEAKER TBA	
6:30 - 8:00PM	*Simultaneous Working Committee Meetings*	
	ABMTR - Breast Cancer Chair: Karen Antman Statistician: Corey Pelz	
	IBMTR - Aplastic Anemia/Fanconi Anemia Chair: Jill Hows Statistician: Kathleen A Sobocinski	
8:00 - 8:30PM	*Coffee Break & Exhibits*	*Exhibit Area*

Monday, January 15 Working Committee Meetings

TENTATIVE PROGRAM

7:00AM -	*Registration/Information Desk*	*Foyer*
8:00 - 9:20AM	*Simultaneous Working Committee Meetings* **ABMTR - Multiple Myeloma** Chair: Sundar Jagannath Statistician: John P. Klein **IBMTR - Metabolic Disorders & Immune Deficiencies** Chair: Alexandra Filipovich Statistician: Corey Pelz	
9:20 - 9:35AM	*Coffee Break & Exhibits*	*Exhibit Area*
9:35 -10:50AM	*Simultaneous Working Committee Meetings* **ABMTR - Lymphoma** Co-Chairs: Hillard Lazarus (HD); Julie Vose (NHL) Statistician: Kathleen A. Sobocinski **IBMTR - Chronic Myelogenous Leukemia** Chair: Phillip McGlave Statistician: Mei-Jie Zhang	
10:50 -11:05AM	*Coffee Break & Exhibits*	*Exhibit Area*
11:05 -12:30AM	*Simultaneous Working Committee Meetings* **ABMTR - Leukemia** Co-Chairs: Armand Keating (AML); Daniel Weisdorf (ALL); Richard Champlin (CLL) Statistician: John Klein **IBMTR - CLL/Lymphoma/Multiple Myeloma** Chair: TBA Statistician: Kathleen A. Sobocinski	
12:30 - 2:00PM	**ABMTR Executive Committee**	*Star Slide Boardroom*
2:00 - 3:30PM	*Working Committee Meeting* **IBMTR - Histocompatibility, Alternative Donors & Stem Cell Sources** Chair: Richard Champlin Statistician: John P Klein	

Register Today!
No Registration Fees for IBMTR/ABMTR Participating Team Members

Questions?
Contact D'Etta Waldoch Koser at IBMTR Statistical Center * 414/ 456-8377 * FAX: 414/ 266-8471

General Information

All members of more than 400 IBMTR- and ABMTR-participating bone marrow transplant centers, representing more than 50 countries, are invited to attend the Working Committee Meetings and Data Management Workshops in Keystone, Colorado. The Data Management Workshops will start on Saturday, January 13; IBMTR and ABMTR Working Committee Meetings will begin on Sunday, January 14 and continue on Monday, January 15 at Keystone Resort. All IBMTR and ABMTR Working Committee members should plan to attend

- **Working Committee Meetings Are Open to All Meeting Participants**

We enthusiastically welcome attendance by senior and junior faculty members, nursing staff and data managers and hope to have each contributing team represented. Non-members are also welcome to take advantage of this opportunity to learn about Statistical Center activities and participate in the scientific program.

Meeting Venue

Keystone Resort has become a favorite venue for many members of the international blood and marrow transplant community over the years. Those who have attended meetings previously at Keystone look forward to returning each year to meet with their colleagues in this familiar and information setting.

Keystone is located approximately 75 miles west of Denver, Colorado, via Route I-70.

In addition to providing the perfect setting for the IBMTR and ABMTR Meetings, Keystone Resort offers lodging, recreational activities, dining, child care facilities and more!

Meeting Registration

- **Registration is easy by fax! Do it today!**
  There are no registration fees for participating IBMTR and/or ABMTR team members.

Please fax the enclosed Registration Form to the Statistical Center today. Don't forget to indicate which Working Committee Meetings you expect to attend. Confirmation for registered participants will be returned by fax.

To join the IBMTR and/or ABMTR contact the Statistical Center

c/o Ms. Sharon Nell
Senior Communications Coordinator
414/ 456-8325 * FAX: 414/ 266-8471
IBMTR/ABMTR Statistical Center
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee, WI 53226 USA

Register *today*!

MEDICAL COLLEGE OF WISCONSIN
CME *program*

Continuing Medical Education

The Medical College of Wisconsin (MCW) is accredited by the U.S. Accreditation Council for Continuing Medical Education to sponsor continuing medical education for physicians. MCW designates this continuing medical education (CME) activity for 19 credit hours in Category I of the Physician's Recognition Award of the American Medical Association for the IBMTR Meeting.

The Medical College of Wisconsin, accredited by the Council on the Continuing Education Unit, certifies that this program meets the criteria for 1.90 Continuing Education Units (CEU).

Participants requesting CME or CEU credit should check the appropriate box on the enclosed Registration Form, and include social security number.

CME/CEU Disclosure

The IBMTR is committed to providing unbiased, balanced and objective educational and scientific programs. In accordance with ACCME guidelines, all IBMTR Meeting speakers were asked to provide relevant disclosure statements, which are on file at the Medical College of Wisconsin Continuing Medical Education office.

High Altitude Warning

Keystone Resort is located 9,300 feet above sea level. If you have any health problems which may be complicated by high altitude, please consult with your physician before registering for the IBMTR/ABMTR Meetings.

Discounted Lift Tickets

Group-rate lift tickets will be available for IBMTR/ABMTR Meeting Participants at $32 per person per day. Lift tickets are good at Keystone, Breckenridge, North Peak and Arapahoe Basin and The Outback.

Questions May Be Directed to:

D'Etta Waldoch Koser, CMP
Associate Director-International Programs
IBMTR/ABMTR Statistical Center, Medical College of Wisconsin
8701 Watertown Plank Road, Milwaukee, WI 53226 USA
telephone: 414/ 456-8377 -or- fax: 414/ 266-8471

IBMTR

Working Committee Meetings & Data Management Workshops

ABMTR

January 13-15, 1996 * Keystone, Colorado

Hotel Accommodations

A limited number of rooms at Keystone Lodge, The Inn, and a variety of 1- and 2-bedroom condominiums are available for Friday, January 12 through Sunday, January 14 for those attending only the IBMTR/ABMTR Meetings. Keystone Resort will make every attempt to accommodate individual requests.

- **Complete the enclosed Housing Form and return it to Keystone Group Reservations prior to December 1, 1995.**
- **Those planning to spend the weekend with the IBMTR/ABMTR *and* attend the Keystone Symposia must complete the official Symposia Housing Form, along with the IBMTR/ABMTR Housing Form.**
- **Questions about Housing? Contact the Keystone Group Reservations Office:**
  PO Box 38, Keystone, Colorado 80435, USA
  Telephone: 970/468-2316 or 800/258-0437
  FAX: 970/468-4543

GROUP NAME:	**IBMTR/ABMTR**	GROUP CODE:	**CA0CIBT**
GROUP DATES:	**January 12-15, 1996**	CUT-OFF DATE:	**December 1, 1995**

You must indicate a major credit card number for a one-night deposit (as directed on the official Housing Form). Reservations will not be held without a deposit. Housing confirmation will be sent directly from Keystone Resort. Reservations made after the cutoff date may not be available at the discounted Meeting rate. Keystone Resort tends to have a 100% occupancy rate each year during the Martin Luther King Holiday Weekend (January 12-14). It may be impossible to accommodate last minute or walk-in requests.

KEYSTONE'S CANCELLATION POLICY IS INDICATED ON THE HOUSING FORM AND WILL BE STRICTLY ENFORCED.

Meeting participants from US institutions which are exempt from their own state sales tax must provide Keystone Resort with a photocopy of the tax exempt certificate, and complete the enclosed State of Colorado Sales and Use Tax Registration Form.

Keystone Resort IBMTR/ABMTR "Group Discount" Room Rates

Keystone Lodge	The Inn	Village Condo Suites	Resort Condo Suites
$145 single	$128 single	$158 studio (up to 2 ppl)	$170 1-bdrm (up to 2 ppl
$160 double	$138 double	$178 1-bdrm (up to 2 ppl)	$255 2-bdrm (up to 4 ppl)
		$275 2-bdrm (up to 4 ppl)	

Register *today*!

Group Travel Assistance

Air Transportation

Special air transportation packages are available through "Meetings & Incentives", independent specialists in medical conferences, worldwide. Discounts are provided on super saver, full coach or first class for IBMTR/ABMTR meeting participants and accompanying persons.

Reservations may be made through "Meetings & Incentives" by calling:
800/ 776-3582 x 107 -or- 414/ 835-3553 x 107
or faxing: 414/ 835-3569
Monday through Friday 8:30am - 5:00pm US Central Time

Please identify yourself as an IBMTR/ABMTR Keystone Meeting participant. Discounted tickets are limited in availability and carry penalties once issued. Wherever possible, seat assignments and boarding cards will be issued per your preference.

Ground Transportation

Hertz

Hertz is the official car rental company for the IBMTR/ABMTR Meeting in Keystone. Special discount meeting rates start from a daily Sub-Compact rate at $28.99 and a weekly Sub-Compact rate at $102.99. Four-wheel drive vehicles are available for mountain driving, starting at $53.99 daily, $219.99 weekly. These rates are guaranteed and available one week before through one week after the meeting dates, subject to car availability, and include unlimited free mileage. In addition, at the time of reservation, when using the Hertz exclusive meeting ID number: CV#17321, Hertz will automatically compare the guaranteed meeting rates to other Hertz published rates to give you the best comparable rate available.

- For reservations, call Hertz at 800/ 654-2240 and refer to CV#17321, or call your travel agent.

When booking through the toll-free number, please identify yourself by the above CV number or identify yourself as an IBMTR/ABMTR Keystone Meeting participant. Standard rental conditions and qualifications apply, including minimum rental age. Check with your Hertz representative for other details.

CAUTION:

Weather at the airport is not a good indication of driving conditions in the mountains. Before heading west on I-70, check the local forecast and road conditions. Inexperienced drivers and those not familiar with driving in winter conditions may wish to use a transportation service, such as Resort Express.

Resort Express

A regularly scheduled shuttle service is available to meet you at the Denver International Airport and deliver you to the Keystone Lodge, with 16 daily departures. It is strongly recommended that reservations be made in advance.

- For more information, call Resort Express 800/334-7433 or 303/468-7600
  Round-trip $64 One-way $32
  Mention the "IBMTR/ABMTR Meeting at Keystone" to obtain discount fares.

IBMTR & ABMTR

Working Committee Meetings & Data Management Workshops

Keystone, Colorado * January 13-15, 1996

featuring:

Scientific Program

*

Working Committee Meetings

*

Data Management Workshops

Scientific Organizing Committee:

Mary M. Horowitz
James O. Armitage
Robert Peter Gale

Exhibits & Sponsorship

A limited amount of space is available for exhibiting. If you are interested in a table top exhibit, or in sponsoring a luncheon or coffee break, please contact:

Ms. Susan Ladwig
Assistant Director of Development, IBMTR/ABMTR
414/ 456-8325, fax: 414/ 266-8471

IBMTR/ABMTR Data Management Workshops
January 13, 1996 Keystone, Colorado
Program Evaluation Summary

	Poor	Fair	Good	Very Good	Excellent
Overall Program					
Topics	0/24	0/24	8/24	11/24	5/24
Speakers	0/22	0/22	7/22	10/22	5/22
Slides/Hand-outs	0/23	2/23	5/23	10/23	6/23
Data Management Sessions - Track I					
Workshop IA	0/19	1/19	1/19	11/19	6/19
Workshop IB	0/14	1/14	2/14	5/14	6/14
Workshop IC	0/18	1/18	2/18	9/18	6/18
Data Management Sessions - Track II					
Workshop IIA	0/7	0/7	3/7	3/7	1/7
Workshop IIB	0/8	0/8	3/8	2/8	3/8
Workshop IIC	0/11	1/11	2/11	4/11	4/11

NOTE: Some participants did not provide answers for all questions.

COMMENTS

Data Management Sessions - Track I:

"I learned a lot and feel much more comfortable."
"Very informative."
"I appreciated very much the information I received..."

Data Management Sessions - Track II:

"Very good introductory talk..."
"well-prepared and good presentation..."
"Terrific presentation, great presentation, well-done..."

DATA MANAGEMENT PARTICIPANTS AT 1996 KEYSTONE MEETINGS

Manuel Abecasis
Instituto Portugues Oncologia, Lisboa, Portugal
Sue Anderson
Saint Francis Hospital, Tulsa, OK
Carmin Apollo
Washington University, St. Louis, MO
Mark Arneson
Arlington Cancer Center, Arlington, TX
*Susan Bach, RN
Cancer and Blood Institute of Desert, Rancho Mirage, CA
*Odette Biron, RN
St. Sacrement, Quebec City, CANADA
Loreen Bonnar
Health Sciences Centre, Winnipeg, CANADA
*Beth A Bonvillain
University of Arkansas, Little Rock, AR
*Daphne A Brockington, HRA
Bone Marrow Transplant Program of British Columbia, Vancouver, BC CANADA
*Christopher Buzzard
The Western Pennsylvania Hospital, Pittsburgh, PA
*Lorraine Cambria
North Shore Hem/Onc Associates, Port Jefferson Station, NY
Fernando Campilal, MD
Instituto Portugues Oncologia, Porto, Portugal
Jeannette Cassar
Childrens Hospital of Orange County, Orange, CA
*Jean Chieppa
St. Charles & Mather Hospital, New York, NY
Gary Choban
Western Pennsylvania Hospital, PA
Sonja J Classen, RN
P/SL Medical Center, Denver, CO
*Sue Corringham, RN
UCSD Cancer Center, San Diego, CA
*Elizabeth Cox
Indiana University Medical Center, Indianapolis
Lorraine Cumbria, RN
North Shore Hem/Onc Associaties, New York
*Christine DeFrancisco
UCSD Cancer Center, San Diego, CA
Susan De Vivo
St. Joseph Hospital & Medical Center
Robert Deves
BMT Unit, Budapest, Hungary
Patricio di Donato
Childrens Hospital of Orange County, Orange, CA
Kathy Dillon
Riverview Cancer Center, New Jersey
Rebecca Eisen
BMT Program of Atlantic Canada/VG Hospital, Halifax, Nova Scotia, CANADA
William Flescher
University of Rochester, Rochester, NY
*Laurie Ann Ford, RRA, BS
Roswell Park Cancer Institute, Buffalo, NY

Emily Fisher
Wilford Hall Medical Center, Lackland AFB, TX
Susan E Gerard
Northeastern Ontario Regional Cancer Centre, CANADA
*Esther Gorelik, RN
University of Pittsburgh, Pittsburgh, PA
*Alison N Greenwald, BS
Jewish Hospital Cincinatti, Cincinatti, OH
Martha Rolland Grinton
Hospital for Sick Children, Toronto, Ontario, CANADA
Amy Hairston
Northwestern University, Evanston, IL
*Susan C Hale, RN
University of Utah, Salt Lake City, UT
Mary Hamielec, RN
University of Wisconsin, Madison, WI
*Josephine Stephenson Hinds, PhD
USC/Norris Cancer Hospital, Los Angeles, CA
*Norine E Huneke
Mayo Clinic Rochester, Rochester, MN
*Debra Ishihara-Wong, RN
The Queen's Medical Center, Honolulu, HI
*Traci H Iwasaki
The Queen's Medical Center, Honolulu, HI
Michelle Jensen
Georgetown University, Washington, DC
Mary Kay Johnston, RN
Abbott Northwestern Hospital-VPCI, Minneapolis, MN
*Terry Wayne Jones, BS
Emory University Hospital, Atlanta, GA
*Michele Joseph
Hopital du Saint Sacrement, Quebec, CANADA
Twila Jukes
University of Kansas Medical Center, KS
Claudia Kabler-Babbitt
Medical College of Wisconsin/Froedtert East Hospital, Milwaukee, WI
*Caren Kauderer
Sutter Memorial Hospital, Sacramento, CA
*Kristen R Kemp, BSN,OCN
St Lukes Medical Center, Milwaukee, WI
Dong-Wook Kim, MD
St. Marys Hospital, Seoul, Korea
*Terry M Koski, RN
Northeastern Ontario Regional Cancer Center, CANADA
*Lori E Kronish, RN
H.Lee Moffitt Cancer Center, Tampa, FL
*Lorriann Langreck
Marshfield Clinic, Marshfield, WI
Jong Lee
St. Mary's Hospital, Seoul, Korea
*Susan B Lerchie, RN
LSU Medical Center-Shreveport, Shreveport, LA
Margaret Lewis
University of Texas Health Sciences Center, San Antonio, TX
Kathy M Lindgren
RMCC/P/SLMC, Denver, CO

*Kathy A Loper, MT(ASCP)
LSU Medical Center-Shreveport, Shreveport, LA
Nadeem Mariza
MD Anderson Cancer Center, Houston, TX
*Jan M McCrae, RN
Toronto General Hospital, Toronto, Ontario CANADA
*Beverly Jane McGloin, BA
University Hospital of Cleveland, Cleveland, OH
*Wendy K McIntyre, RN
St Louis University Health Sciences Center, St Louis, MO
Tom Miller
Rocky Mountain Cancer Center, Denver, CO
Pamela Monroe, RN
Washoe Medical Center
*Mary E Morris, RN
University of Nebraska Medical Center, Omaha, NE
*Lolly Naslund, RRA,CTR
VirginiaPiper Cancer Institute/Abbott NW Hospital, Minneapolis, MN
*Sheryl L Oliversen, RN
So Texas Cancer Institute, San Antonio, TX
*Barbara Phlaum
Cancer & Blood Institute of the Desert, Rancho Mirage, CA
*Jene L Pierson
University of Nebraska Medical Center, Omaha, NE
*Carlene Porter
Rush Presbyterian St Lukes Medical Center, Chicago, IL
David Rice
University of Kentucky, Lexington, KY
*Colleen M Rivera, RN
St Joseph Hospital, Orange, CA
Shari Rottman
Childrens Hospital of Denver, CO
Jean Sabatos
St. Josephs Medical Center
*Ruth Santucci Beale, RN
Sutter Memorial Hospital, Sacramento, CA
*Galina Sapozhnikova
University Hospitals of Cleveland, Cleveland, OH
Louis Schweichler
Arlington Cancer Center, Arlington, TX
*Chris Scott
University of North Carolina, Chapel Hill, NC
*Linda M Simpson, CTR
Hoag Memorial Hospital, Newport Beach, CA
*Paula J Smith, Data Coordinator
Bowman Gray School of Medicine, Winston Salem, NC
*Betsy A Stein, CCRC
Baylor University Medical Center, Dallas, TX
*Mary C Swinney, RN
Methodist of IN, Inc, Indianapolis, IN
*Rosalie S Sziarto, RN
Northside Hospital, Atlanta, GA
*Nancy Tainer
University Hospitals of Cleveland, Cleveland, OH
Miki Takahashi
Tokai University, Japan

Nita Takeuchi
BC Childrens Hospital, Vancouver, BC, CANADA
Dixon Terry
Arkansas Cancer Research Center, Little Rock, AR
Mark R Tindall
Emory University Hospital, Atlanta, GA
Zutaka Tokuda, MD
Tokai University, Japan
*Renee A Vadeboncoeur, RN
University of Utah, Salt Lake City, UT
Marlies Van Hoef, MD
Sunnyvale, CA
Twilla Westercamp, RN
Truman Medical Center
Michael Wierman, MD
St. Vincent Hospital, Indianapolis, IN
*Diana D Wilson
Case Western Reserve Univ, Cleveland, OH
*Rita Winter
Via Christi Regional Medical Center, Wichita, KS

*received grant for partial travel expenses

ABMTR
North America
Autologous Blood & Marrow Transplant Registry

AUDIT PROGRAM FOR CENTERS PARTICIPATING IN THE ABMTR-North America

I. Objectives

To verify consecutive case reporting and accuracy of reported data as compared to institutional medical records.

II. Audit Operations

Participating institutions are at risk of being audited once every three years. Each year, one third of institutions contributing reports to the ABMTR are notified that they may be audited in the ensuing 12 months. From that list, 20 institutions are selected at random. For each of the 20, an Advisory Committee member near the institution is identified and three convenient times chosen for the audit. Auditors are asked to sign a waiver indicating they have no political, financial or other conflict of interest with the team to be audited prior to notifying the team leader of the identity of the auditor. If the team leader perceives that there may be a bias on the part of the selected auditor, team leaders are given one week to request another auditor. If none is available from among Advisory Committee members in the immediate vicinity, a member of the Statistical Center will perform the audit. The institution to be audited is notified and a final date agreed upon. Three weeks prior to the date of audit, the institution is notified of ten cases selected at random from among its contributions during the preceding five years. The audited institution is expected to have medical records and all necessary supporting information gathered and available at the time of the audit for each of these ten cases.

III. Verification of Consecutive Reporting

Cases reported to the ABMTR by the audited team for one year in the five years prior to the audit will be compared by the auditor to institutional records of all transplants performed, to verify that all eligible cases were reported. The auditor will verify that records of the transplant program confirm reporting.

IV. Verification of Accurate Reporting

At the time of the audit, the auditor selects five of the ten available cases for detailed review. For these five cases, specific items reported on ABMTR data collection forms are compared with data in the institutional medical record. Deficits and discrepancies are documented by question number and discrepancy, using a form-specific checklist prepared by the ABMTR Statistical Center and the Executive Committee.

V. Assistance with the Audit

The data manager and/or transplant coordinator of the audited institution will function as an assistant to the Advisory Committee member performing the audit. The assistant locates information required in the medical record (based on information provided by the Statistical Center) prior to the time of the on-site audit to expedite retrieval and verification by the auditor. The assistant also provides documentation of consecutive patients transplanted at the time of the audit.

VI. Analysis of Audits

The Auditor is responsible for preparing an analysis of the audit to include consideration of the following:

1. Questionable or falsified reporting forms, that is, reporting forms submitted to the ABMTR describing patients who are not documented by a medical record;

2. Misinterpretation of instructions or questions such that incorrect answers are submitted;

3. Discrepancies between data found in the medical record and on the ABMTR reporting form;

4. Failure to provide required follow-up.

Audit analyses are done using a form provided by the Statistical Center. Analyses are submitted to the Audit Committee within 30 days of completing the audit.

VII. Review of Audits

The Audit Committee will review each Audit Analysis and prepare an Audit Report to be sent to the audited institution and the Executive Committee within 30 days of receiving the Audit Analysis. This report may contain recommendations for improvement in local data management. Institutions that the Audit Committee considers suspect for fraud, biased reporting and/or serious deficiencies in data management are referred to the Executive Committee for further action.

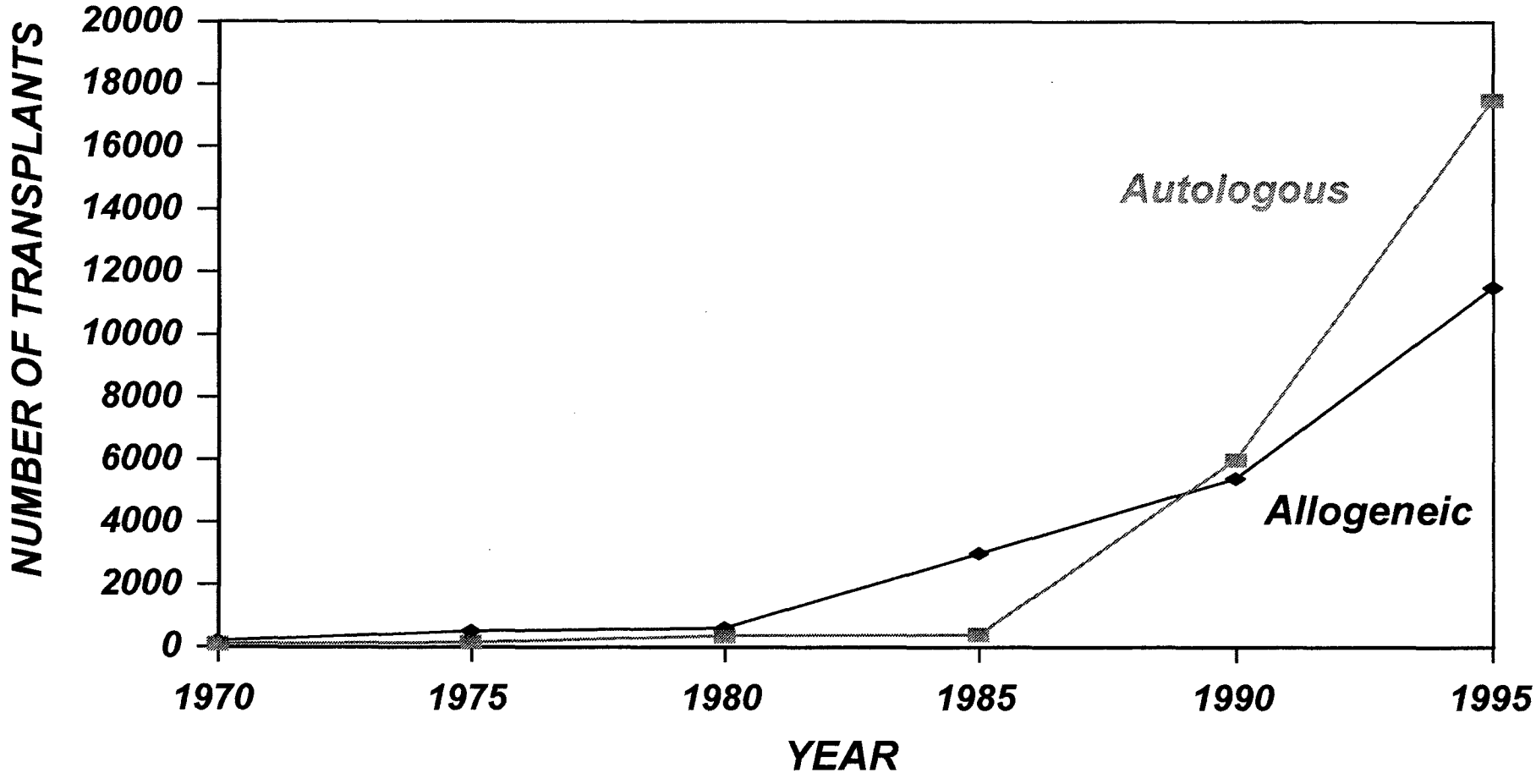
VIII. Audit Summaries

The Audit Committee prepares an annual report of all audits for the ABMTR Executive Committee. The Executive Committee is responsible for summarizing these reports for ABMTR annual progress reports and the annual meeting of the ABMTR Advisory Committee.

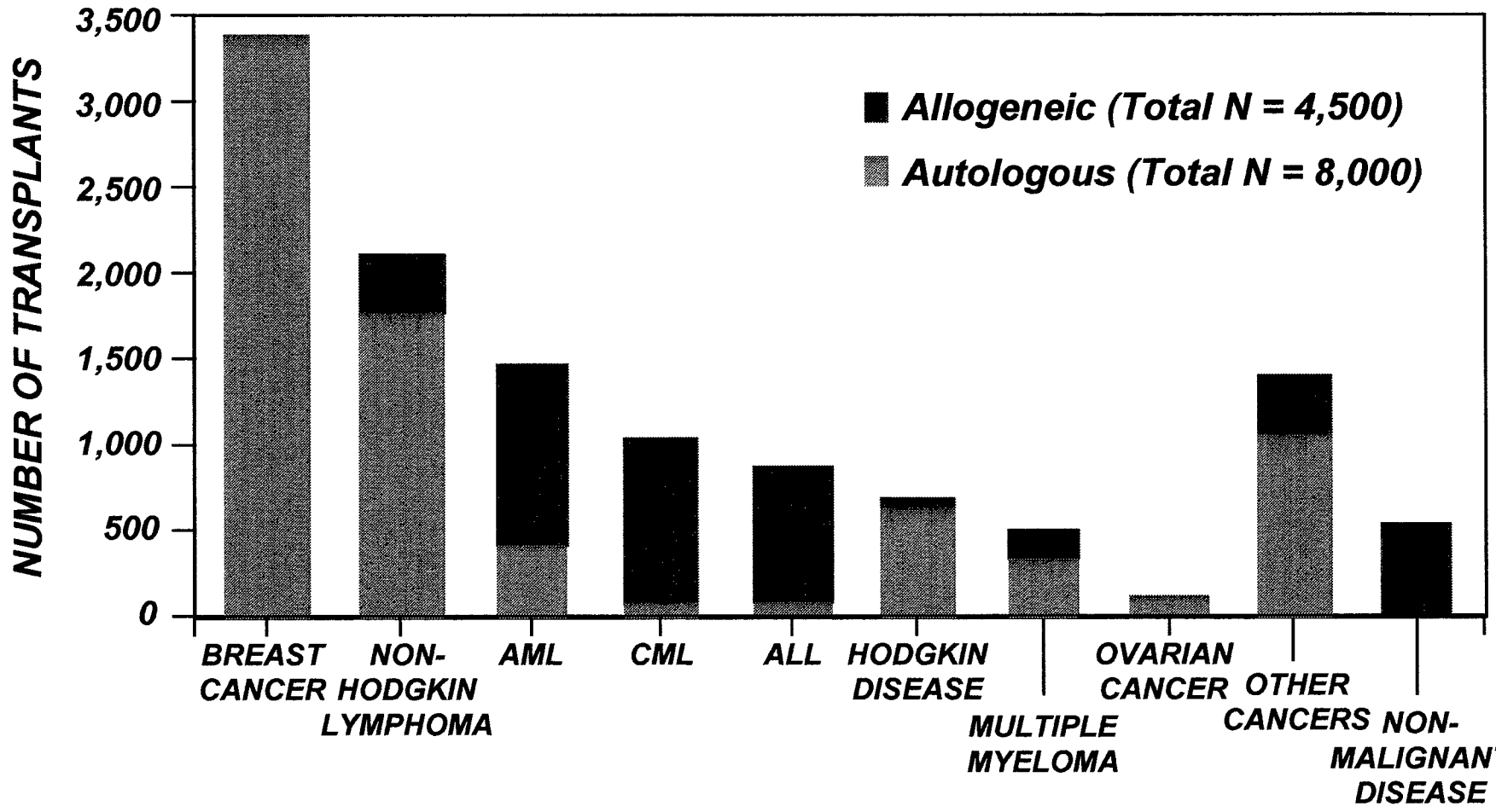
IX. Consequences of Fraudulent, Non-consecutive and/or Inaccurate Reporting

As noted above, institutions with serious deficiencies are referred to the Executive Committee for action. Instances in which fraud is suspected may result in additional requests for documentation and additional audits. If fraud is documented, the institution is denied further participation in ABMTR activities and all data previously reported to the ABMTR removed from the ABMTR database. In the event of failure to report consecutive cases, an institution is given 120 days to rectify the deficiency by reporting all omitted cases and is subject to re-audit in 12 months. Failure to remedy the deficiency results in suspension and removal of all data previously reported by the offending institution from the database. Serious inaccuracies in data reported to the IBMTR are brought to the attention of the offending institution with recommendations for remedial action. The institution is subject to re-audit within 12 months. Whether previously reported cases are deleted from the ABMTR database is at the discretion of the Executive Committee after consideration of audit findings.

ANNUAL NUMBER OF BLOOD AND MARROW TRANSPLANTS WORLDWIDE 1970-1995

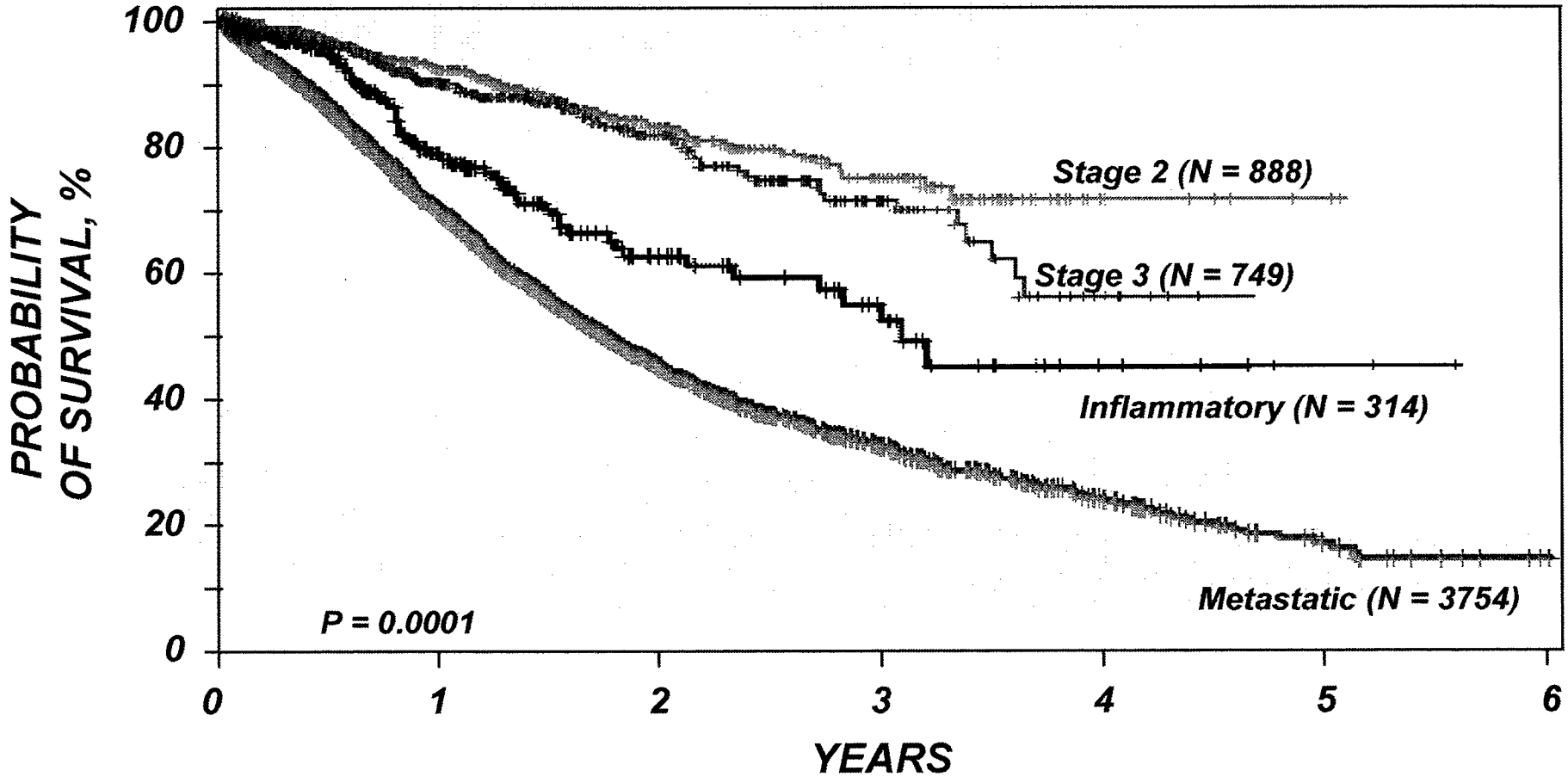


INDICATIONS FOR BLOOD AND MARROW TRANSPLANTATION IN NORTH AMERICA 1995



SUM24.ppt

PROBABILITY OF SURVIVAL AFTER AUTOTRANSPLANTS FOR BREAST CANCER 1989-1995



U.S. CENTERS RESPONDING TO INSTITUTIONAL SURVEY

ALABAMA
Brookwood Medical Center, Birmingham
University of Alabama at Huntsville, Huntsville
University of South Alabama, Mobile

ARIZONA
University of Arizona Health Sciences Center, Tucson

CALIFORNIA
Alta Bates Medical Center, Comprehensive Cancer Center, Berkeley
University of California, San Diego, La Jolla
University of California, Irvine, Newport Beach
Children's Hospital of Orange County (CHOC), Orange
St. Joseph Hospital, Orange
Sutter Memorial Hospital, Sacramento
University of California, Davis Cancer Center, Sacramento
Children's Hospital of San Diego, San Diego
University of San Diego , San Diego
University of California - San Francisco, Moffitt Hospital, San Francisco
John Muir Hospital, Walnut Creek
Westlake Comprehensive Cancer Center, Westlake Village

COLORADO
Presbyterian-St. Luke's Medical Center, Denver

CONNECTICUT
Yale University School of Medicine / New Haven Hospital, New Haven
Bennett Cancer Center, Stamford

DELAWARE
Medical Center of Delaware / Christiana Hospital, Newark

FLORIDA
Impact Center of Clearwater, Clearwater
Bone Marrow Stem Cell Institute of Florida, Ft. Lauderdale
Impact Center of South Broward, Ft. Lauderdale
University of Florida, J. Hillis Miller Health Center, Gainesville
Baptist Regional Cancer Center, Jacksonville
Mayo Clinic Jacksonville/St. Luke's Hospital, Jacksonville
Baptist Hospital of Miami, Miami
All Children's Hospital, St. Petersburg
H. Lee Moffitt Cancer Center & Research Institute, Tampa

GEORGIA
Egleston Hospital for Children at Emory University, Atlanta
Emory University Hospital / The Emory Clinic, Atlanta

IOWA
University of Iowa Hospital & Clinics, Iowa City

ILLINOIS
Children's Memorial Medical Center, Chicago
University of Chicago Medical Center, Chicago
Loyola University Cancer Center, Maywood
Lutheran General Hospital / University of Chicago, Park Ridge

INDIANA
Impact Center of Ft. Wayne / Ft. Wayne Medical Oncology-Hematology, Ft. Wayne
Methodist Hospital of Indiana, Indianapolis
St. Vincent Hospital & Health Care Center, Indianapolis

KANSAS
Children's Mercy Hospital, Kansas City
University of Kansas Medical Center, Kansas City
St. Francis Hospital, Wichita

KENTUCKY
Kosair Children's Hospital, Louisville

LOUISIANA
Mary Bird Perkins Cancer Center, Baton Rouge
Children's Hospital, New Orleans / Louisiana State University, New Orleans
Tulane University Medical Center / Tulane Cancer Center, New Orleans
Louisiana State University Medical Center-Shreveport, Shreveport

MASSACHUSETTS
Beth Israel Health Care Charles C. Shapiro Cancer Center, Boston
Brigham & Women's Hospital, Boston
Children's Hospital of Boston / Dana-Farber Cancer Institute, Boston
Dana-Farber Cancer Institute, Boston
Massachusetts General - MGH East, Boston
Massachusetts General Hospital, Boston
Cancer Center of Boston, Plymouth
Baystate Medical Center / Tufts University School of Medicine, Springfield
Medical Center of Central Massachusetts, Worcester
University of Massachusetts Medical Center, Worcester

MARYLAND
University of Maryland Cancer Center, Baltimore
Holy Cross Hospital, Silver Spring

MAINE
Maine Medical Center, South Portland

MICHIGAN
Henry Ford Hospital, Detroit

MINNESOTA
Abbott Northwestern Hospital, Minneapolis
University of Minnesota Hospital & Clinics, Minneapolis
Mayo Clinic & Foundation, Rochester
Methodist Hospital & Park Nicollet Cancer Center, St. Louis Park

MISSOURI
Mid America Medical Consultants, Kansas City
Barnes Hospital / Washington University Medical Center , St. Louis
Cardinal Glennon Children's Hospital, St. Louis
St. Louis Children's Hospital / Washington University School of Medicine, St. Louis

NORTH CAROLINA
University of North Carolina, Chapel Hill
North Carolina Baptist Hospital/Bowman Gray School of Medicine, Winston-Salem

NEBRASKA
Immanuel Cancer Center, Omaha
University of Nebraska Medical Center, Omaha

NEW HAMPSHIRE
Dartmouth-Hitchcock Medical Center, Lebanon

NEW JERSEY
St. Joseph's Hospital & Medical Center, Paterson
Riverview Medical Center, Red Bank

NEVADA
Washoe Regional Cancer Center / University of Nevada School of Medicine, Reno

NEW YORK
Albany Medical Center, Albany
Montefiore Medical Center, Bronx
Schneider Children's Hospital, New Hyde Park
Columbia Presbyterian Medical Center, New York
Mount Sinai Medical Center, New York
St. Charles & John T. Mather Hospital / North Shore Stem Cells, Port Jefferson Station
University Hospital-SUNY Health Sciences Center, Syracuse

OHIO
Children's Hospital Medical Center, Cincinnati
Jewish Hospital of Cincinnati, Cincinnati
Rainbow Babies and Children's Hospital / University Hospitals of Cleveland, Cleveland
A.G. James Cancer Hospital & Research Institute / Ohio State University Hospitals, Columbus
Columbus Children's Hospital, Columbus
Miami Valley Hospital, Dayton

OKLAHOMA
University of Oklahoma Health Sciences Center, Oklahoma City
St. Francis Hospital, Tulsa

PENNSYLVANIA
Fox Cancer Center, Philadelphia
Temple University Comprehensive Cancer Center, Philadelphia
Thomas Jefferson University Hospital, Philadelphia
University of Pennsylvania Hospital, Phildelphia
Children's Hospital of Pittsburgh, Pittsburgh
Shadyside Hospital, Pittsburgh
Western Pennsylvania Cancer Institute, Pittsburgh

SOUTH CAROLINA
Medical University of South Carolina / Hollings Cancer Center, Charleston
Richland Memorial Hospital / University of South Carolina, Columbia

TENNESSEE
Methodist Hospital Central, Memphis
St. Jude's Children's Research Hospital, Memphis

TEXAS
Southwest Regional Cancer Center, Austin
Baylor University Medical Center, Dallas
Children's Medical Center of Dallas, Dallas
Cook-Fort Worth Children's Medical Center, Fort Worth
Harris Methodist Oncology Program, Fort Worth
Texas Children's Hospital, Houston
Audie L. Murphy Memorial Veterans Hospital, San Antonio
Wilford Hall Medical Center, San Antonio

UTAH
Intermountain Health Care, Inc., LDS Hospital, Salt Lake City
Oncology Clinical Trials Office, Salt Lake Clinic, Salt Lake City
University of Utah Medical Center, Salt Lake City

VERMONT
Fletcher Allen Health Care / UHC Campus, Burlington

WASHINGTON
Seattle Department of Veterans Affairs Medical Center, Seattle

WASHINGTON, DC
Georgetown University Medical Center
Pasquerilla Healthcare / Vincent T. Lombardi Cancer Research Center
Walter Reed Army Medical Center

WISCONSIN
University of Wisconsin Hospital & Clinics, Madison
Marshfield Clinic, Marshfield
Medical College of Wisconsin, Froedtert East Hospital, Milwaukee
St. Luke's Medical Center, Milwaukee

WEST VIRGINIA
West Virginia University Hospitals, Morgantown

IBMTR
International Bone Marrow Transplant Registry

IBMTR/ABMTR

ABMTR
North America
Autologous Blood & Marrow Transplant Registry

Survey of Transplant Activity 1991-1995

Name of Institution: _____

Director of Transplant Program: _____

Address: _____

_____

_____

_____

Country: _____

Telephone Number: _____

FAX Number: _____

e-mail Address: _____

Transplant Coordinators: _____

_____

_____

Person completing this form: _____

Date completed: ☐☐ ☐☐ ☐☐
Month Day Year

Other Bone Marrow Transplant Physicians at your Institution

Please list other members of your bone marrow transplant team. This information will be used to compile a *Directory of Bone Marrow Transplant Physicians* which will be distributed to all centers participating in the survey.

If this information is included on your institution's letterhead, simply attach a sheet, OR simply attach the business card of each member of the transplant team. Please attach additional pages if necessary.

Last Name	First Name	Middle Name	Degree(s)	Division/Department	Address (if different)	Telephone	Fax	e-mail Address

REGISTRY USE ONLY

IBMTR International Bone Marrow Transplant Registry

IBMTR/ABMTR

ABMTR North America Autologous Blood & Marrow Transplant Registry

Survey of Transplant Activity 1991-1995

During the years 1991 through 1995, were any of the following done at your transplant center?

	Yes	No	Don't Know
1. **Autologous** bone marrow transplantation	1 ☐	0 ☐	8 ☐
2. **Autologous** peripheral stem cell transplantation	1 ☐	0 ☐	8 ☐
3. **Allogeneic** bone marrow transplantation	1 ☐	0 ☐	8 ☐
4. **Allogeneic** peripheral stem cell transplantation	1 ☐	0 ☐	8 ☐
5. **Cord blood** transplantation	1 ☐	0 ☐	8 ☐

6. Number of cord blood transplants in 1995: ☐☐

7. Is your center/unit primarily:

1 ☐ Community

2 ☐ Academic

3 ☐ Other, SPECIFY: _____

8. Is your center/unit affiliated with an academic center?

1 ☐ Yes, specify: _____

0 ☐ No

9. What is the total number of beds at your hospital?

1 ☐ <100
2 ☐ 100-199
3 ☐ 200-299
4 ☐ 300-399
5 ☐ 400-499
6 ☐ ≥500
8 ☐ Don't know

10. Does your hospital treat only cancer patients?

1 ☐ Yes
0 ☐ No

11. Does your center have dedicated transplant beds?

1 ☐ Yes
0 ☐ No

12. Number of dedicated transplant beds: ☐☐☐☐

REGISTRY USE ONLY

13. How many separate bone marrow and/or peripheral stem cell transplant units (or teams) are physically located at your center? *[NOTE: Separate units/teams are defined as units with separate administrative and clinical personnel.]*

1 ❑ One unit
0 ❑ More than one unit

14. Would you describe your transplant unit as primarily:
1 ❑ Pediatric 2 ❑ Adult 3 ❑ Combined

15. Number of units: ☐

How would you characterize or distinguish each of these units (eg. breast cancer, autologous, etc.)?

16. Unit 1: _____ Contact person: _____
17. Unit 2: _____ Contact person: _____
18. Unit 3: _____ Contact person: _____
19. Unit 4: _____ Contact person: _____
20. Unit 5: _____ Contact person: _____

Would you describe these transplant units as primarily pediatric, adult or combined units?

	Pediatric	Adult	Combined
21. Unit 1:	1 ❑	2 ❑	3 ❑
22. Unit 2:	1 ❑	2 ❑	3 ❑
23. Unit 3:	1 ❑	2 ❑	3 ❑
24. Unit 4:	1 ❑	2 ❑	3 ❑
25. Unit 5:	1 ❑	2 ❑	3 ❑

26. If your center has more than one transplant unit, please indicate whether responses to the following questions in this survey pertain to all units or one unit.

1 ❑ All units
2 ❑ One unit

27. Indicate which unit *(as numbered in Questions 7-14)*:
1 ❑ Unit 1
2 ❑ Unit 2
3 ❑ Unit 3
4 ❑ Unit 4
5 ❑ Unit 5

28. If you answered "yes" to question 1 and/or 2, when did your center/unit first perform autologous bone marrow and/or peripheral stem cell transplants? 19 ☐☐

29. If you answered "yes" to question 3, 4, or 5, when did your center/unit first perform allogeneic, related donor bone marrow and/or peripheral stem cell and/or cord blood transplants? 19 ☐☐

REGISTRY USE ONLY

30. If you answered "yes" to question 3, 4 and/or 5, when did your center/unit first perform allogeneic, unrelated donor bone marrow and/or peripheral stem cell and/or cord blood transplants?

19☐☐ OR -7 ☐ do not perform unrelated donor transplants

31. Do medical students or physicians in postgraduate training work on your transplant unit?

1 ☐ Yes
0 ☐ No

32. Does your center/unit treat patients only on clinical study protocols, only off-protocol or both?

1 ☐ Only on clinical study protocols
2 ☐ Only off-protocol
3 ☐ Both on and off-protocol

33. Does your center/unit perform any chemotherapy followed by stem cell reinfusion that is entirely on an outpatient basis?

1 ☐ Yes
0 ☐ No
8 ☐ Don't know

34. For how many of the patients who received a transplant at your center/unit in 1995 was pretransplant conditioning (high dose therapy) administered entirely on an outpatient basis? ☐☐☐

Does your center/unit regularly perform:

	Yes	No	Don't Know
35. Chemical purging to remove tumor cells from autografts	1 ☐	0 ☐	8 ☐
36. Gene therapy studies	1 ☐	0 ☐	8 ☐
37. Negative selection with monoclonal antibodies	1 ☐	0 ☐	8 ☐
38. Positive selection with CD34 monoclonal antibodies	1 ☐	0 ☐	8 ☐
39. Ex vivo expansion of marrow-derived cells	1 ☐	0 ☐	8 ☐
40. Ex vivo expansion of blood-derived cells	1 ☐	0 ☐	8 ☐
41. T-cell depletion	1 ☐	0 ☐	8 ☐

42. Which one of the following agents are primarily used for priming or mobilization for autologous peripheral stem cell collection at your center/unit? **(CHECK ONE)**

1 ☐ G-CSF alone
2 ☐ G-CSF plus some chemotherapeutic agent
3 ☐ GM-CSF alone
4 ☐ GM-CSF plus some chemotherapeutic agent
5 ☐ A chemotherapeutic agent alone
6 ☐ Other agent or combination of agents, PLEASE SPECIFY: _____
7 ☐ None

REGISTRY USE ONLY

43. Which one of the following agents are primarily used for priming or mobilization for allogeneic peripheral stem cell collection at your center/unit? **(CHECK ONE)**

1 ❑ G-CSF alone
2 ❑ G-CSF plus some chemotherapeutic agent
3 ❑ GM-CSF alone
4 ❑ GM-CSF plus some chemotherapeutic agent
5 ❑ A chemotherapeutic agent alone
6 ❑ Other agent or combination of agents, PLEASE SPECIFY: _____
7 ❑ None

44. Do you currently have a computerized system for capturing and analyzing clinical data on your transplant patients? *(Do not include systems used primarily for billing purposes unless specifically designed to be suitable for clinical studies.)*

1 ❑ Yes
0 ❑ No

45. Type of computer used:

1 ❑ IBM-compatible PC
2 ❑ Macintosh
3 ❑ Workstation
4 ❑ Mainframe

46. Database used:

1 ❑ FoxPro
2 ❑ dBase
3 ❑ Paradox
4 ❑ Sybase
5 ❑ Oracle
6 ❑ Stem Soft
7 ❑ Other, specify: _____

47. ***(U.S. and Canada only)*** What is the average nurse/patient ratio on your inpatient allogeneic transplant unit?

1 ❑ 1:2
2 ❑ 1:3
3 ❑ 1:4
4 ❑ <1:4
-8 ❑ Don't know

48. ***(U.S. and Canada only)*** What is the average nurse/patient ratio on your inpatient autologous transplant unit?

1 ❑ 1:2
2 ❑ 1:3
3 ❑ 1:4
4 ❑ <1:4
-8 ❑ Don't know

REGISTRY USE ONLY

(U.S. only) As best you can, please estimate what percent of autologous transplants at your center/unit are paid by the following mechanisms:

49. Negotiated fixed price (eg. as with managed care) ☐☐☐ %

50. Traditional fee-for-service ☐☐☐ %

51. Discounted fee-for-service ☐☐☐ %

52. Hospital-absorbed cost for indigent patient ☐☐☐ %

(U.S. only) As best you can, please estimate what percent of allogeneic transplants at your center/unit are paid by the following mechanisms:

53. Negotiated fixed price (eg. as with managed care) ☐☐☐ %

54. Traditional fee-for-service ☐☐☐ %

55. Discounted fee-for-service ☐☐☐ %

56. Hospital-absorbed cost for indigent patient ☐☐☐ %

57. ***(U.S. only)*** Do any of the bone marrow and/or peripheral stem cell transplants performed at your center/unit involve a commercial enterprise such as Response Technologies, Caremark, Salick, and/or TOPA in any way?

1 ☐ Yes
0 ☐ No

With which particular commercial enterprises is your center/unit involved as part of its transplant program?

	Yes	No	
58.	1 ☐	0 ☐	Response Technologies
59.	1 ☐	0 ☐	Caremark
60.	1 ☐	0 ☐	Salick
61.	1 ☐	0 ☐	TOPA
62.	1 ☐	0 ☐	Other, SPECIFY: _____

63. For what percent of the transplants performed at your center/unit do these organizations play some role? ☐☐☐ %

REGISTRY USE ONLY

Is your center/unit a member of **(CHECK ALL THAT APPLY)**:

	Yes	No	
64.	1 ☐	0 ☐	International Bone Marrow Transplant Registry (IBMTR)
66.	1 ☐	0 ☐	Autologous Blood & Marrow Transplant Registry of North America (ABMTR)
68.	1 ☐	0 ☐	European Blood and Marrow Transplant Group (EBMTG)
69.	1 ☐	0 ☐	National Marrow Donor Program (NMDP)
70.	1 ☐	0 ☐	Cooperative clinical trials group(s), specify:

65. Team Number ☐☐☐

67. Team Number ☐☐☐

	Yes	No			Yes	No	
71.	1 ☐	0 ☐	EORTC	**78.**	1 ☐	0 ☐	NSABP
72.	1 ☐	0 ☐	MRC	**79.**	1 ☐	0 ☐	NCCOG
73.	1 ☐	0 ☐	ECOG	**80.**	1 ☐	0 ☐	RTOG
74.	1 ☐	0 ☐	CALGB	**81.**	1 ☐	0 ☐	Other, specify: _____
75.	1 ☐	0 ☐	SWOG	**82.**	1 ☐	0 ☐	Other, specify: _____
76.	1 ☐	0 ☐	POG	**83.**	1 ☐	0 ☐	Other, specify: _____
77.	1 ☐	0 ☐	CCSG	**84.**	1 ☐	0 ☐	Other, specify: _____

On the following tables, please provide the number of transplants done in each year (1991-1995) by disease and graft type.

TABLE 1 - **1991**

DONOR SOURCE, No. of transplants done in **1991**

INDICATION	**Autologous**				**Allogeneic**								
					Family						Unrelated		
					HLA-identical sibling		Other		Twin				
	BM only	PB only	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	Total
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast, inflammatory													
Breast, metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE: ____ ____ ____ ____

TABLE 2 - **1992**

DONOR SOURCE, No. of transplants done in 1992

INDICATION	**Autologous**				**Allogeneic**								
					Family						Unrelated		
					HLA-identical sibling		Other		Twin				
	BM only	PB only	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	Total
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast, inflammatory													
Breast, metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE: ____ ____ ____ ____

TABLE 3 - **1993**

DONOR SOURCE, No. of transplants done in **1993**

INDICATION	**Autologous**				**Allogeneic**								
					Family						Unrelated		
					HLA-identical sibling		Other		Twin				
	BM only	PB only	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	Total
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast, inflammatory													
Breast, metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE: ____ ____ ____ ____

TABLE 4 - **1994**

INDICATION	DONOR SOURCE, No. of transplants done in **1994**												
	Autologous				**Allogeneic**								
					Family						Unrelated		
					HLA-identical sibling		Other		Twin				
	BM only	PB only	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	Total
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast, inflammatory													
Breast, metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE: ____ ____ ____ ____

TABLE 5 - **1995**

DONOR SOURCE, No. of transplants done in **1995**

INDICATION	**Autologous**				**Allogeneic**								
					Family						Unrelated		
					HLA-identical sibling		Other		Twin				
	BM only	PB only	BM + PB	Total	BM	PB	BM	PB	BM	PB	BM	PB	Total
Acute myeloid leukemia 1st complete remission													
not 1st complete remission													
Acute lymphoblastic leukemia 1st complete remission													
not 1st complete remission													
Chronic myeloid leukemia 1st chronic phase													
not 1st chronic phase													
Myelodysplastic syndrome													
Chronic lymphocytic leukemia													
Multiple myeloma													
Hodgkin's lymphoma													
Non Hodgkin lymphoma													
Neuroblastoma													
Glioma													
Soft tissue sarcoma													
Germinal tumors													
Breast cancer stage 2													
Breast cancer stage 3													
Breast, inflammatory													
Breast, metastatic													
Ewing													
Lung cancer													
Other solids tumors													
Severe aplastic anemia													
Fanconi Anemia													
Thalassemia													
SCID													
Inborn errors													
Auto immune disease													
Others													
TOTAL													

BM: bone marrow; PB: peripheral blood progenitor cells

REGISTRY USE: ____ ____ ____ ____

HIGH-DOSE CHEMOTHERAPY WITH AUTOLOGOUS HEMATOPOIETIC STEM CELL SUPPORT FOR BREAST CANCER IN NORTH AMERICA

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Running Head: Autotransplants for Breast Cancer in North America

ABSTRACT

Purpose: Identify trends in high-dose therapy with autologous hematopoietic stem cell support (autotransplants) for patients with breast cancer from 1989 to 1995.

Patients and Methods: Analysis of observational database of the Autologous Blood and Marrow Transplant Registry of North America (ABMTR). Data on 19,291 autotransplants between 1989 and June 30, 1995 were reviewed; 5,886 were performed for breast cancer. Patients received high-dose chemotherapy (with or without radiation therapy) with autologous hematopoietic stem cell support. Main outcome measures were progression-free survival (PFS) and survival from time of autotransplant.

Results: Use of autotransplants for breast cancer increased six-fold between 1989 and 1995. After 1992, breast cancer was the most common indication for autotransplant. Significant trends included increasing use for locally advanced (stages 2 and 3) rather than metastatic (stage 4) disease ($p<0.00001$) and use of blood- rather than bone marrow-derived cells ($p<0.00001$). Treatment-related mortality decreased substantially from 22% in 1989 to 5% in 1995 ($p<0.0001$).

Three-year probabilities of PFS (95% confidence intervals) were 65 (59-71)% for women with stage 2 breast cancer and 60 (53-67)% for those with stage 3 breast cancer. Three-year probabilities of survival were 74 (68-80)% and 70 (63-77)% for stage 2 and 3 breast cancer, respectively among women with stage 4 breast cancer, three-year probabilities of PFS and survival were 7 (4-10)% and 16 (12-20)%, respectively, for those with stable or progressive disease after conventional dose chemotherapy; 13 (9-17)% and 29 (25-33)% for those with a partial response to conventional chemotherapy, and 32 (27-37)% and 46 (42-50)% for those with a complete response to conventional chemotherapy. Eleven percent of women with stage 2 or 3 disease and fewer than 1% of those with stage 4 disease participated in national cooperative

group randomized trials.

Conclusions: Autotransplants are increasingly used to treat breast cancer and are now the most common indication for transplant. Treatment-related mortality has decreased substantially. Three-year survival is better in women with stage 2 and 3 versus stage 4 disease and in those responding to pretransplant chemotherapy.

INTRODUCTION

Breast cancer is the most common cancer and the second most common cause of cancer deaths in American women.[1] Survival of women with breast cancer correlates with extent of disease. Ten-year survival is 65-80% for women with disease confined to the breast.[2-4] Ten-year survival rates are 35-65% for those with 1-3 involved axillary lymph nodes, 30-40% for those with 4-9 involved axillary nodes and 15-30% in those with >9 involved axillary nodes.[5-7] Recurrent disease tends to develop earlier in patients with multiple involved nodes and relapse risk persists for at least 20 years after mastectomy. Women with metastatic breast cancer have a median survival of about two years and a 2-5% probability of five-year disease-free survival.[8-11]

Intensive therapy (chemotherapy with or without radiation therapy) with autologous hematopoietic stem cell support (autotransplant) is increasingly used to treat breast cancer in women at high risk of persistent or recurrent disease. However, most reports of autotransplants include relatively few subjects and there are likely to be substantial reporting biases. One small randomized study of women with metastatic breast cancer shows a statistically significant advantage in both survival and disease-free survival for high-dose chemotherapy with bone marrow transplant versus conventional dose chemotherapy.[12] Here we report results of autotransplants in more than 5800 consecutive women receiving autotransplants at over 130 centers between 1989 and 1995.

METHODS

Patients: The Autologous Blood and Marrow Transplant Registry of North America (ABMTR) is a voluntary organization of more than 170 transplant institutions in the United States, Canada, and Central and South America that report data on consecutive autotransplants to a Statistical Center at the Medical College of Wisconsin. An autotransplant is defined as treatment with a sufficiently high dose of chemotherapy to require autologous bone marrow or blood-derived hematopoietic stem cell support. The Statistical Center also collects data for allogeneic bone marrow transplants (allotransplants) from centers participating in the International Bone Marrow Transplant Registry, a similar but independent organization of allotransplant centers worldwide.

The ABMTR began data collection in 1992. Data were collected retrospectively for patients receiving autotransplants between 1989 and 1992 and prospectively thereafter. Participating centers register core information on consecutive autotransplants for all disease indications. Based on data collected in the Center for Disease Control Hospital Surveys[13,14], about half of North American autotransplants for all diseases were registered with the ABMTR during the study period. A list of participating centers is shown in Appendix 1. Registration data from consecutive women with breast cancer receiving an autotransplant at ABMTR centers between January 1989 and June 30, 1995 were the subject of this analysis.

Data regarding disease type, age, gender and posttransplant survival were requested for all patients. Questions regarding pretransplant disease stage and chemotherapy-responsiveness, date of diagnosis, graft type (bone marrow and/or blood-derived stem cells), high-dose conditioning regimen and posttransplant disease progression were added to registration forms more recently. Although an attempt was made to collect this information for previously registered patients, these data are not available for all patients. Patients with primary (stages 2, 3 and inflammatory) and

metastatic breast cancer were considered separately in the analysis. The ABMTR requests data on progression or death in registered patients at six month intervals.

Statistical Methods: Comparisons of patient and treatment characteristics over time used chi-square test for categorical and Kruskal-Wallis test for continuous variables.[15] Probabilities of 100-day mortality, progression-free survival (PFS) and overall survival were calculated using the Kaplan-Meier product limit estimate.[16] Comparisons of 100-day mortality, PFS and survival between groups used the log rank test.[17]

RESULTS

Between January 1, 1989 and June 30th, 1995, 19,291 patients receiving high-dose therapy with autologous hematopoietic stem cell support were reported to the ABMTR. Of these, 5,886 (31%) were for breast cancer. Between 1989 and 1995, autotransplants for breast cancer increased from 16% to 40% ($P<0.00001$) of all autotransplants reported (Figure 1, Table 1). Numbers of autotransplants for breast cancer exceeded those for Hodgkin disease and non-Hodgkin lymphoma after 1992. Breast cancer was the most common indication for stem cell transplants of all types in 1993-94 (Figure 1).

Numbers of patients reported per year, age at transplant, pretransplant disease stage, source of stem cells, and treatment-related mortality are shown in Table 1. The distribution of disease stage at transplantation changed from 7% local and 93% metastatic disease in 1989 to about 50% local and 50% metastatic disease in 1995 ($P<0.00001$). This is reflected in the interval from diagnosis to transplant which decreased over the study period. By 1995, 57% of transplants for breast cancer were done within one year of diagnosis.

Use of blood-derived cells alone or in combination with bone marrow increased from 19% to

90% (P<0.00001) in these six years. Various preparatory regimens were used with only the combination of cyclophosphamide, thiotepa and carboplatin (CTCb) used in more than 25% of all patients. An important finding was decreasing 100-day mortality, from 22% in 1989 to 5% in 1995 (P<0.00001).

High-Risk Primary Breast Cancer

Characteristics of women receiving autotransplants for Stage 2, 3 and inflammatory breast cancer are shown in Table 2. Eleven percent were treated as part of randomized cooperative group trials. While most patients had stage 2 or 3 breast cancer and 10 or more involved axillary nodes, some transplants were done for inflammatory breast cancer (17%) or for women with <10 axillary nodes involved (28%). Kaplan-Meier estimates of survival and PFS by disease stage are shown in Figure 2; three-year probabilities are listed in Table 3.

Metastatic Breast Cancer

Characteristics of women receiving autotransplants for metastatic breast cancer are shown in Table 4. Fewer than 1% were treated on randomized cooperative group trials. Most patients had chemotherapy-sensitive disease (complete or partial response prior to transplant) and either visceral or bone disease. Median survival was 19 months (Figure 2). Three-year PFS and survival probabilities are shown in Table 3. Women with a complete response to chemotherapy pretransplant had superior survival and PFS to those with either a partial response or resistant disease (Figure 3).

Second Malignancies

Data regarding second malignancies were available for 2,045 women. There were 13 cancers reported: 4 myelodysplastic syndromes, 2 endometrial carcinomas, 1 ovarian carcinoma, 1 squamous cell carcinoma, 1 transitional cell carcinoma of the bladder, 1 Hurthle cell tumor of the thyroid, 1 lung carcinoma, 1 glioblastoma, and 1 cervical cancer.

DISCUSSION

These data indicate several interesting aspects of autotransplants for breast cancer. First, the annual frequency of autotransplants has increased substantially, from fewer than 300 reported to the ABMTR in 1989 to about 1,500 presently. Second, an increasing proportion are for women with locally advanced disease: <10% in 1989 versus about 50% presently. As a correlate, the interval from diagnosis to transplant has decreased substantially; <20% of transplants were done within 1 year of diagnosis in 1989 versus >50% presently. A third trend is increasing use of blood- rather than marrow-derived grafts: 14% in 1989 versus >70% presently. Finally, treatment-related mortality also decreased substantially, from >20% in 1989 versus 5% presently. This probably reflects several factors including selection of patients with less advanced disease and better performance status.

Women with locally advanced (stage 2 and 3) breast cancer receiving autotransplants differ from the general population of women presenting with breast cancer. Median age was 44 years and more than 70% had >9 involved lymph nodes. These data contrast with typical women with breast cancer whose median age is about 60, of whom about 5% have >9 involved lymph nodes.[6,7] These differences reflect the substantial selection factors for transplant and underscore the importance of comparing autotransplants and chemotherapy in comparable subjects. A Toronto

study reported that 28% of patients referred for one randomized trial of high versus lower dose therapy were ineligible because of occult metastatic disease identified by the required pre-transplant evaluation.[18] Thus, differences observed between transplanted patients and patients receiving conventional dose chemotherapy in historical data bases may result from selection of patients without occult metastases.

Women with metastatic (stage 4) disease receiving autotransplants were also somewhat atypical. Median age was 44 years and 58% had cancers with estrogen receptors. About 28% had a complete response to chemotherapy, but 24% had disease progression. These data contrast with typical women with stage 4 breast cancer whose median age is about 60 years, of whom about 60-70% have cancers with estrogen receptors. These differences again underscore the importance of comparing autotransplants and chemotherapy in comparable subjects. Nevertheless, one small randomized study shows a statistically significant advantage in both survival and disease-free survival for high-dose chemotherapy with bone marrow transplant versus conventional dose chemotherapy.[12]

Results of autotransplants correlated with disease stage. Women with stage 2 or 3 disease had better PFS and survival than those with stage 4 disease. There was, however, no difference in PFS or survival between women with stage 2 versus 3 disease. Among women with metastatic (stage 4) disease, those with a complete response to pretransplant chemotherapy did better than those with a partial response. The latter did better than those with stable disease or progression. Women with tumors unresponsive to lower dose treatment are unlikely to achieve long term disease-free survival after autotransplant.

The correlation between stage and chemotherapy response and outcome is not surprising. Similar results are reported for conventional treatments. Better transplant outcome in "better"

subjects does not mean that transplants should be performed earlier or indicate whether transplants are better than conventional therapy. These questions are best addressed in prospective studies, several of which are underway (Table 5). However, randomized trials, one of which has been reported[12], and those listed in Table 5, are not designed to answer other important questions such as relative efficacy of various high-dose regimens, supportive care technologies, or even patient, disease and treatment-related factors important for transplant outcome. The ABMTR is an important resource for addressing such issues. Data collected by the Centers for Disease Control hospital survey[13,14] suggest that about half of all autotransplants in North America are reported the ABMTR. We believe reporting of autotransplants for breast cancer is similar, making available a substantial and likely representative proportion of cases for study. Registry audits ensure that this sample is unselected and that data are accurate. Registry data will be critical for extrapolating results of randomized trials, which tend to be applied in restricted populations, to other patients and in evaluating the impact of preparative regimens, demographic factors and prior treatment and other variables. Thus registry data provide an important observational database with which to monitor trends and assess new technology and will complement data from randomized trials.

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FIGURE LEGENDS

Figure 1: Numbers of allotransplants (hematopoietic stem cells collected from a donor) and autotransplants by year by disease for most common indications.

Figure 2: Kaplan-Meier estimates of progression-free survival (PFS) (2a) and survival (2b) after autotransplants for primary (stage 2, 3 or inflammatory) and metastatic breast cancer.

Figure 3. Kaplan-Meier estimates of progression-free survival (PFS) (3a) and survival (3b) after autotransplant for metastatic breast cancer by responsiveness to chemotherapy pretransplant. CR=complete response to conventional dose chemotherapy pretransplant, PR=partial response and Resistant=stable or progressive disease pretransplant.

Table 1. Autotransplants for breast cancer registered with the ABMTR.

	1989	1990	1991	1992	1993	1994	Jan-June 1995	P-value
Number (N)	272	342	683	1069	1189	1513	818	
Percent of all autotransplants registered:								
	16%	16%	25%	33%	33%	39%	40%	<0.00001
Autotransplants for breast cancer:								
Number of centers reporting	34	45	66	85	99	105	101	
Median transplants/center	3 (1-58)	5 (1-44)	6 (1-44)	7 (1-71)	6 (1-59)	8 (1-86)	5 (1-63)	0.005
Stage immediately prior to high-dose chemotherapy and autotransplant:								
N evaluable[a]	213	313	650	1005	1088	1404	721	<0.00001
Local disease[b]	7%	16%	23%	34%	31%	39%	49%	
Metastatic	93%	83%	77%	65%	68%	60%	50%	
Other[c]	<1%	1%	< 1%	1%	1%	1%	1%	
Age								
N evaluable	272	341	678	1059	1123	1461	817	<0.00001
Median (range) yrs	41 (23-64)	42 (24-66)	44 (22-72)	44 (25-65)	45 (24-66)	45 (22-69)	45 (22-71)	
Interval, diagnosis to transplant								
N evaluable	237	299	614	960	1106	1392	774	<0.00001
<1 yr	18%	24%	31%	44%	42%	49%	57%	
1-2 yrs	28%	19%	16%	14%	12%	13%	10%	
>2 yrs	54%	57%	53%	42%	46%	38%	33%	

Table 1, continued

Graft type								
N evaluable	162	215	474	813	1189	1447	760	<0.00001
BM	81%	79%	58%	42%	30%	19%	10%	
BM + PBSC	5%	7%	22%	33%	30%	25%	18%	
PBSC	14%	14%	20%	25%	40%	56%	72%	
Conditioning regimen								
N evaluable	140	183	423	735	870	1174	587	<0.00001
CBP	7%	4%	11%	13%	9%	14%	6%	
CT	25%	22%	23%	23%	21%	21%	21%	
CTCb	18%	16%	15%	28%	37%	39%	44%	
CTM	6%	2%	6%	4%	4%	2%	1%	
ICE	3%	10%	8%	7%	6%	4%	4%	
CTHu	8%	4%	5%	4%	3%	3%	4%	
CEP	3%	3%	5%	3%	2%	1%	2%	
Other	30%	37%	27%	18%	18%	16%	18%	
100-day mortality								
N evaluable	265	340	679	1034	1153	1366	784	<0.00001
%	22%	15%	11%	6%	6%	4%	5%	

[a]Information for all variables not available for all patients; registration forms were revised in 1992 and 1993 to capture additional information.

[b]Local disease = stage 2, 3 and inflammatory breast cancer

[c]Patients with locally persistent or recurrent disease post conventional therapy.

Abbreviations: BM, bone marrow; PBSC, peripheral blood stem cells; C, cyclophosphamide; B, BCNU; P, cisplatin; T, thiotepa; Cb, carboplatin; M, mitoxantrone; I, ifosfamide; E, etoposide; Hu, hydroxyurea

Table 2. Autotransplants for Stage 2, 3 or inflammatory breast cancer.

	N evaluable[a]	N	(%)[b] (range)[c]
Number registered	1,747		---
Age, years (median)	1,731	44	(22-69) y
Stage pretransplant	1,613[d]		
2		750	(46%)
3		603	(37%)
Inflammatory		260	(17%)
Months from diagnosis to transplant	1,636	7	(2-16)
Number of nodes positive	542		
< 10		150	(28%)
≥ 10		392	(72%)
ER receptor positive	479	298	(62%)
Principal adjuvant chemotherapy			
CAF	491	314	(64%)
Graft type	1,527		
BM		502	(32%)
BM + PBSC		450	(30%)
PBSC		555	(38%)
High-dose chemotherapy regimen used:	1,370		
CT		432	(32%)
CTCb		403	(29%)
CBP		220	(16%)
CTM		52	(4%)
ICE		78	(6%)
CEP		26	(2%)
Other		156	(11%)
100-day mortality (%)	1,668		(3%)

[a]Information for all variables not available for all patients. Registration forms were revised in 1992 and 1993 to capture additional information.

[b]For categorical variables

[c]For continuous variables

[d]134 additional patients stage 2 versus 3 versus inflammatory not specified

Abbreviations: ER, estrogen receptor; C, cyclophosphamide; A, doxorubicin (Adriamycin); F, fluorouracil; BM, bone marrow; PBSC, peripheral blood stem cells; B, carmustine (BCNU); P, cisplatin, T, thiotepa; Cb, carboplatin; M, mitoxantrone; E, etoposide; Hu, hydroxyurea

Table 3. Three-year Kaplan-Meier estimates of progression-free (PFS) and overall survival after autotransplants for breast cancer.

Stage	PFS	95 % CI	Survival	95 % CI
2 2 to 5 cm or involved lymph nodes	65%	59-71%	74%	68-80%
3 > 5 cm or fixed to the chest wall	60%	53-67%	70%	63-77%
Inflammatory	42%	31-53%	52%	40-64%
4 Metastatic	18%	16-20%	30%	28-32%
Response to chemotherapy:				
In complete remission	32%	27-37%	46%	40-52%
In partial remission	13%	9-17%	29%	25-33%
Not responding	7%	4-10%	16%	12-20%

Table 4. Autotransplants for metastatic breast cancer.

	N evaluable[a]	N	(%)[b] (range)[c]
Number registered	3451		
Age, years (median)	3398	44	(22-72) y
Sensitivity to chemotherapy pretransplant	3411		
Complete or partial response		2134	(63%)
Stable or progressive disease		595	(17%)
Undetermined		682	(20%)
Sites of metastatic disease	1212		
Viscera (no CNS)[d]		593	(49%)
Bone or bone marrow ± soft tissue[e]		328	(27%)
Soft tissue alone		273	(23%)
CNS[f]		18	(1%)
ER receptor positive	1203	700	(58%)
Interval, diagnosis to transplant	3298		
< 1 yr		687	(21%)
1-2 yrs		568	(17%)
> 2 yrs		2038	(62%)
Graft type	3018		
BM		993	(33%)
PBSC		1373	(46%)
BM + PBSC		652	(21%)

Table 4, continued

Conditioning regimen	2522		
CTCb		899	(36%)
CT		416	(17%)
ICE		132	(5%)
CTHu		146	(6%)
CTM		71	(3%)
CBP		202	(8%)
CEP		60	(2%)
Other		596	(23%)
100-day mortality (%)	3395		(10%)

a Information for all variables not available for all patients. Registration forms were revised in 1992 and 1993 to capture additional information.

b For categorical variables

c For continuous variables

d Includes patients with or without bone, bone marrow, or soft tissue involvement

e Excludes patients with visceral or CNS involvement

f Includes patients with or without visceral, bone, bone marrow, or soft tissue involvement

Abbreviations: CNS, central nervous system; ER, estrogen receptor; BM, bone marrow; PBSC, peripheral blood stem cells; C, cyclophosphamide; B, carmustine (BCNU); P, cisplatin, T, thiotepa; Cb, carboplatin; M, mitoxantrone; E, etoposide; Hu, hydroxyurea

Table 5. Ongoing randomized trials of autotransplants in breast cancer by stage.

Eligible Stage	Study Sponsor	Standard Initial Therapy	High-dose Regimen	Control
Stage 2				
Number of involved lymph nodes				
≥ 4	Milan/Italy	None	HDS	E x 3, CMF x 6
≥ 4	Inter-Scandinavian	CEF x 4	CTCb	CEF x 4
≥ 4	Italian	CEF x 4	CEL	CEF x 2
≥ 4	Dutch	CEF x 4	CTCb	CEF x 1
4-9	Duke	AF	CBP	no more therapy vs. CBP alone
≥ 6	ICG (Manchester)	CE x 4	CTCb	CE x 4
≥ 8	SFGM/FNCCC	CEF x 4	CMitoxL	no further therapy
≥ 10 or > 4 high risk	IBCSG		CE x 3	AC or EC x 4, then CMF x 3
≥ 10	CALGB	CAF x 4	CBP	conventional dose CBP
≥ 10	German Multicenter	CE x 4	CTMitox	CMF x 3
≥ 10	ECOG	CAF x 4	CT	no further therapy
Stage 3				
	Milan/Italy	None	HDS	E x 3, then CMF x 6
	SFGM/FNCCC	Chemo x 4	CMitoxL	conventional chemotherapy
	IBCSG		CE x 3	AC or EC x 4, then CMF x 3
	CALGB	A x 4	CTCb	continuous CMF x 16 weeks
	German Multicenter	CE x 4	CTMitox	CMF x 3
Stage 4				
	Duke (CRs only)	AFM x 4	CBP	CBP at relapse
	Duke (bone only)	AFM x 4, radiation	CBP	CBP at relapse
	Phila Intergroup	CAF x 6	CTCb	CMF x 2 years
	SFGM/FNCCC	Chemo x 4	CMitoxL	conventional chemotherapy

Legend: ICG, International Collaborative Group (Manchester), SFGM, Societe Francaise de Greffe du Muelle; FNLCC; Federation Nationale des Centres de Lulte Centra le Cancer; CALGB, Cancer and Leukemia Group B; ECOG, Eastern cooperative oncology group; SWOG, Southwest Oncology Group; IBCSG International breast Cancer Study Group; C, cyclophosphamide; E, epirubicin; A, doxorubicin (Adriamycin); F 5-fluorouracil; Cb, carboplatin; M, methotrexate; P, cisplatin; L, melphalan; Mitox, mitoxantrone; T, thiotepa; HDS high-dose sequential therapy

Appendix 1. Institutions reporting breast cancer cases to the ABMTR.

Country, Institution	City
Argentina	
Alexander Fleming Institute	Buenos Aires
Centro de Internacion e Investigation	Buenos Aires
Hospital Privado de Oncologia	Buenos Aires
Navy Hospital "Pedro Mallo"	Buenos Aires
Hospital Privado de Cordoba	Cordoba
Austria	
Donauspital	Vienna
Brazil	
Hospital de Clinicas	Curitiba
Hospital Nossa Senhora das Gracas	Curitiba
Canada	
University of Calgary	Calgary
Royal Victoria Hospital	Montreal
Sacré Coeur Hospital	Montreal
Northeastern Ontario Regional Cancer Centre	Sudbury
Toronto Hospital	Toronto
Vancouver General Hospital	Vancouver
Manitoba Cancer Treatment Center	Winnipeg

Cuba	
Hermanos Ameijeiras Hospital	Havana
Mexico	
Institute Nacional de Cancerologia	Mexico City
Centro de Hematologia y Medicina Interna	Puebla
Russia	
Petrov Research Institute of Oncology	St. Petersburg
United States	
Presbyterian Health Care Services	Albuquerque
University of Michigan Medical Center	Ann Arbor
Arlington Cancer Center	Arlington
Emory Clinic	Atlanta
Southwest Regional Cancer Center	Austin
Johns Hopkins Hospital	Baltimore
University of Maryland Cancer Center	Baltimore
Mary Bird Perkins Cancer Center	Baton Rouge
Alta Bates Hospital	Berkeley
University of Alabama at Birmingham	Birmingham
Dana-Farber Cancer Institute	Boston
Montefiore Medical Center	Bronx
Roswell Park Cancer Institute	Buffalo
University of North Carolina Chapel Hill	Chapel Hill
Medical University of South Carolina	Charleston

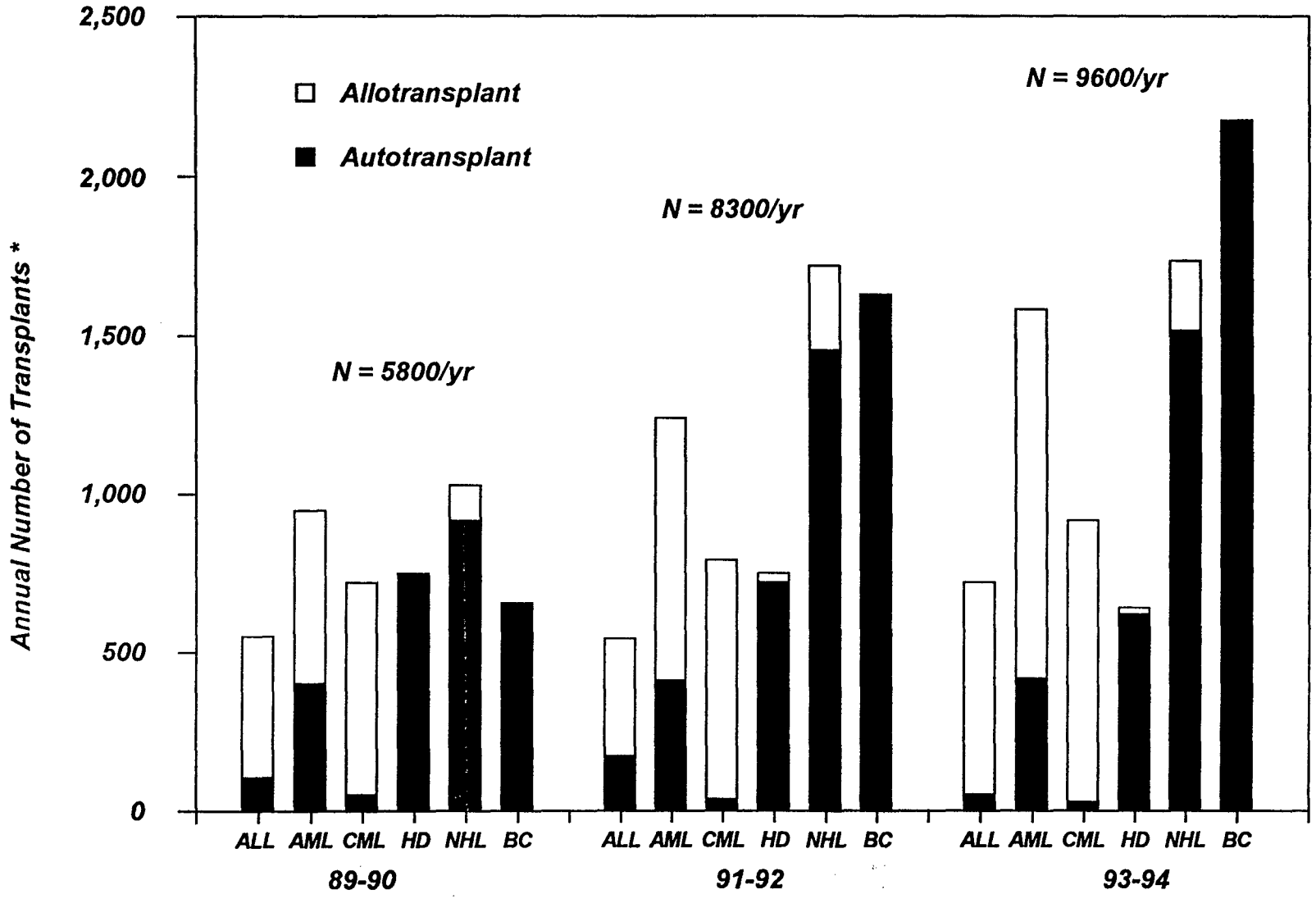
University of Virginia Medical Center	Charlottesville
Rush Presbyterian/St. Luke's Medical Center	Chicago
University of Chicago Medical Center	Chicago
Jewish Hospital of Cincinnati	Cincinnati
University Hospital Cincinnati	Cincinnati
Case Western Reserve University Hospital	Cleveland
Cleveland Clinic Foundation	Cleveland
University of South Carolina	Columbia
Ohio State University Hospital	Columbus
Baylor University Medical Center	Dallas
Miami Valley Hospital	Dayton
Presbyterian/St. Luke's Hospital	Denver
Wayne State University	Detroit
City of Hope National Medical Center	Duarte
University of Connecticut Health Center	Farmington
Bone Marrow & Stem Cell Institute of Florida	Fort Lauderdale
Harris Methodist Oncology Program	Fort Worth
University of Florida, Shands Hospital	Gainesville
East Carolina University School of Medicine	Greenville
Hackensack Medical Center	Hackensack
Hinsdale Hematology-Oncology Associates	Hinsdale
Queen's Cancer Center	Honolulu
St. Francis Medical Center	Honolulu

Baylor College of Medicine	Houston
M.D. Anderson Cancer Center	Houston
Indiana University Hospital & Outpatient Center	Indianapolis
Methodist Hospital of Indiana	Indianapolis
St. Vincent Hospital & Health Care Ctr.	Indianapolis
Baptist Regional Cancer Center	Jacksonville
University of Kansas Medical Center	Kansas City
Scripps Clinic & Research Foundation	La Jolla
Dartmouth-Hitchcock Medical Center	Lebanon
University of Kentucky Medical Center	Lexington
University of Arkansas for Health Sciences	Little Rock
UCLA Center for Health Sciences	Los Angeles
USC/Norris Cancer Hospital	Los Angeles
James Graham Brown Cancer Center	Louisville
University of Wisconsin	Madison
North Shore University Hospital	Manhasset
Marshfield Clinic	Marshfield
Loyola University Medical Center	Maywood
Methodist Hospital Central	Memphis
Baptist Hospital of Miami	Miami
Froedtert East Hospital	Milwaukee
St. Luke's Medical Center	Milwaukee
Abbott Northwestern Hospital	Minneapolis

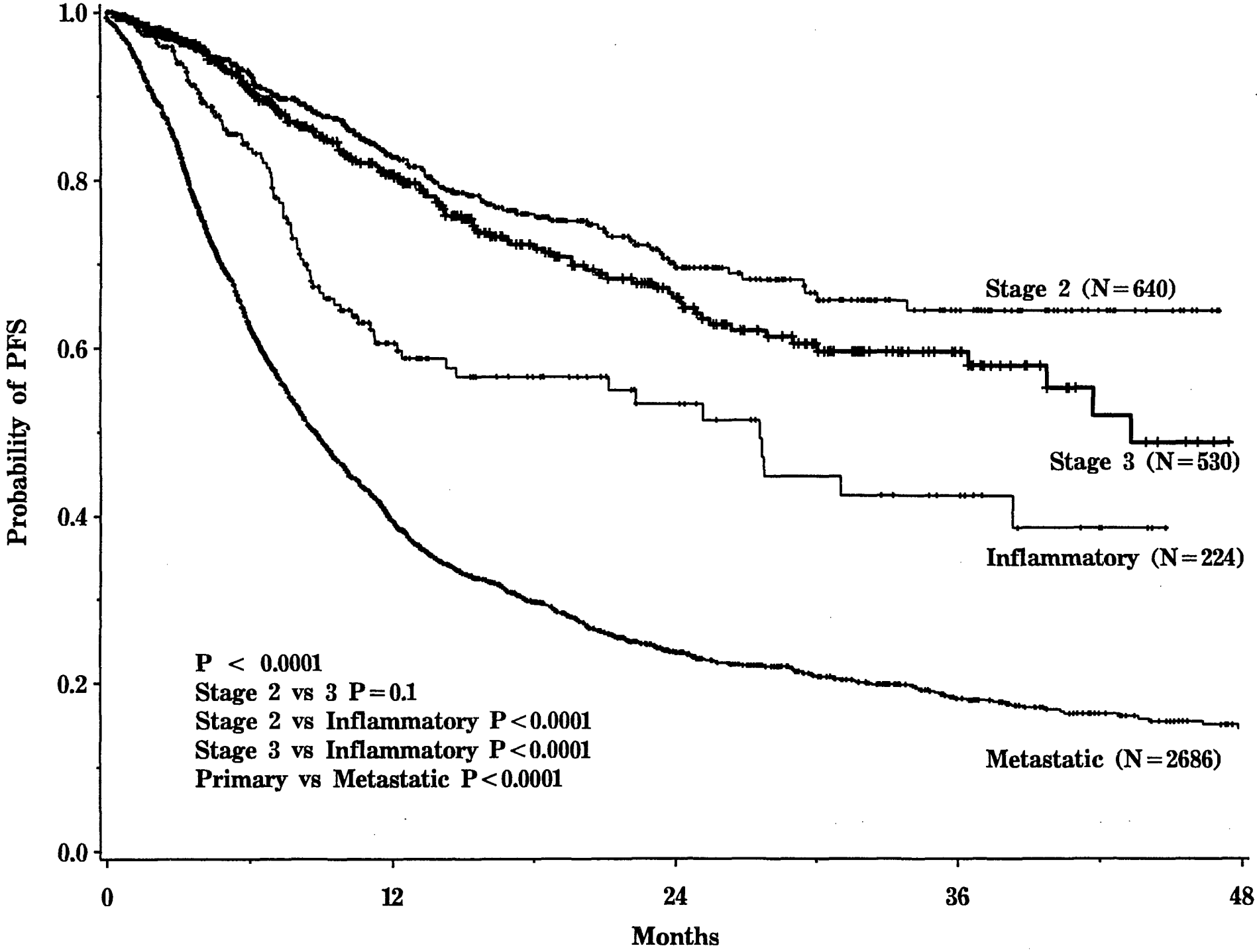
University of Minnesota	Minneapolis
West Virginia University	Morgantown
Vanderbilt University Medical Center	Nashville
Columbia Presbyterian Medical Center	New York
Mount Sinai Medical Center	New York
Medical Center of Delaware	Newark
Hoag Cancer Center	Newport Beach
University of Oklahoma Health Sciences Center	Oklahoma City
University of Nebraska Medical Center	Omaha
Saint Joseph Hospital	Orange
Lutheran General Hospital	Park Ridge
Hematology Associates	Peoria
Hahnemann University Hospital	Philadelphia
Temple University Comprehensive Cancer Center	Philadelphia
University of Pennsylvania Hospital	Philadelphia
Shadyside Hospital	Pittsburgh
University of Pittsburgh	Pittsburgh
Cancer Center of Boston	Plymouth
St. Charles & John T. Mather Hospital	Port Jefferson Station
Oregon Health Sciences Univ.	Portland
Roger Williams Medical Center	Providence
Cancer & Blood Institute of the Desert	Rancho Mirage
Washow Regional Cancer Center	Reno

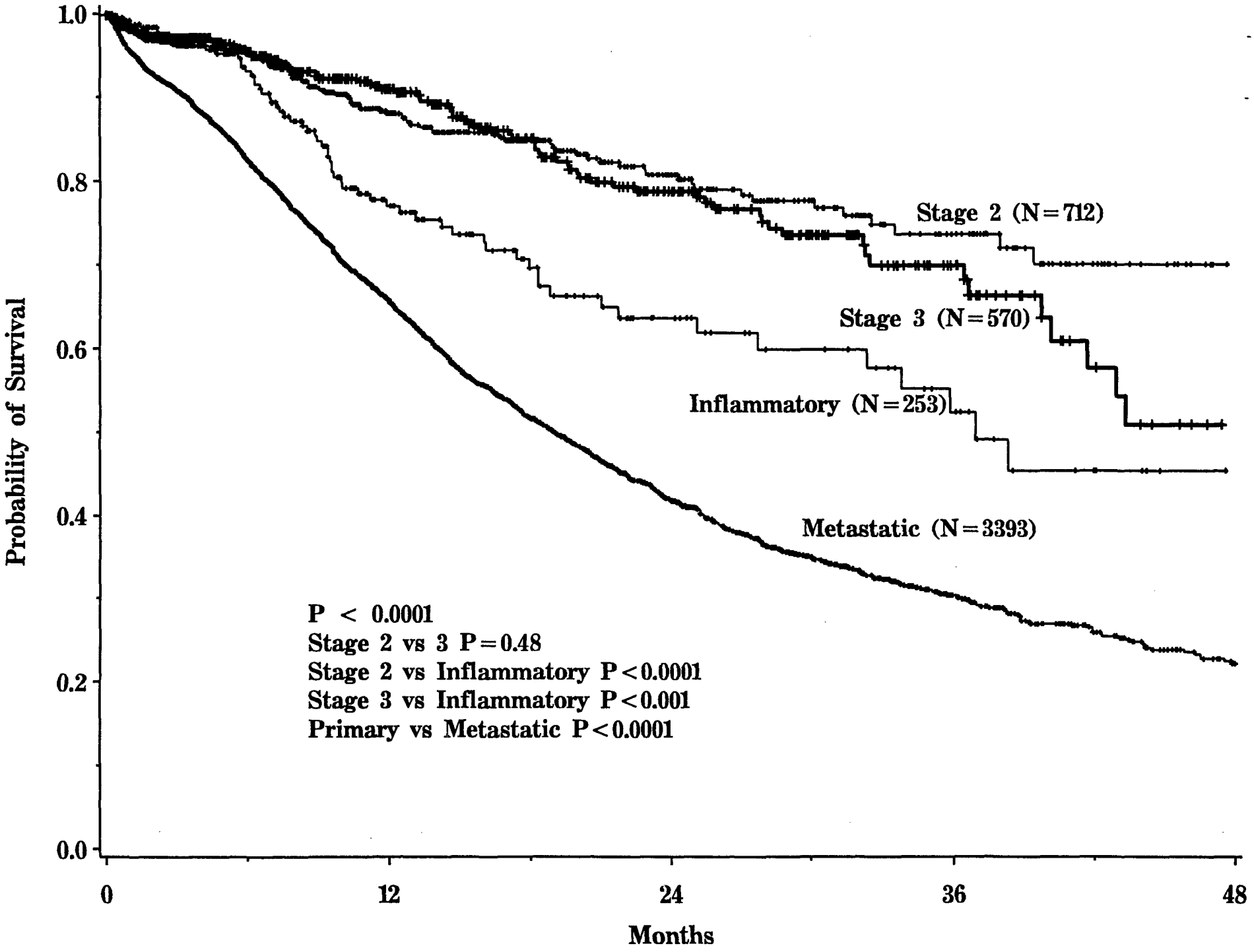
Mayo Clinic Rochester	Rochester
University of Rochester	Rochester
Sutter Memorial Hospital	Sacramento
University of California Davis Cancer Center	Sacramento
Latter Day Saints Hospital	Salt Lake City
University of Utah Medical Center	Salt Lake City
South Texas Cancer Institute	San Antonio
University of Texas Health Sciences Center	San Antonio
University of CA, San Diego	San Diego
University of CA, San Francisco Medical Center	San Francisco
Mayo Clinic Scottsdale	Scottsdale
LSU Medical Center-Shreveport	Shreveport
Memorial Medical Center	Springfield
Tufts University School of Medicine	Springfield
Methodist Hospital/Nicollet Cancer Center	St. Louis Park
St. Louis University Medical Center	St. Louis
Bennett Cancer Center	Stamford
Stanford University Hospital	Stanford
SUNY-Health Science Center	Syracuse
H. Lee Moffitt Cancer Center	Tampa
Arizona Cancer Center	Tucson
St. Francis Hospital	Tulsa
New York Medical College	Valhalla

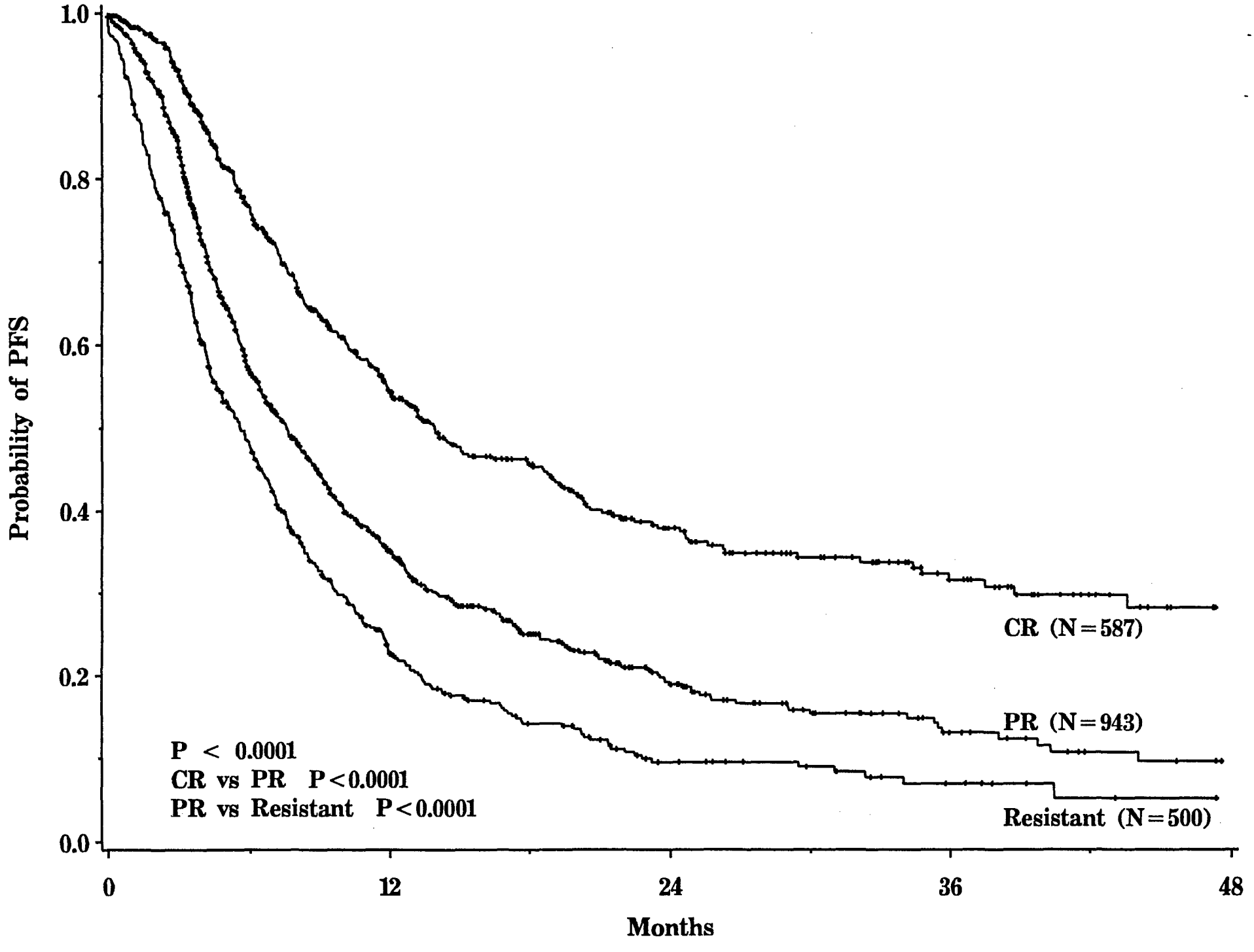
George Washington University Medical Ctr.	Washington, D.C.
Walter Reed Army Medical Center	Washington, D.C.
Westlake Comprehensive Cancer Center	Westlake Village
St. Francis Hospital	Wichita
Wake Forest University	Winston-Salem
University of Massachusetts Medical Center	Worcester

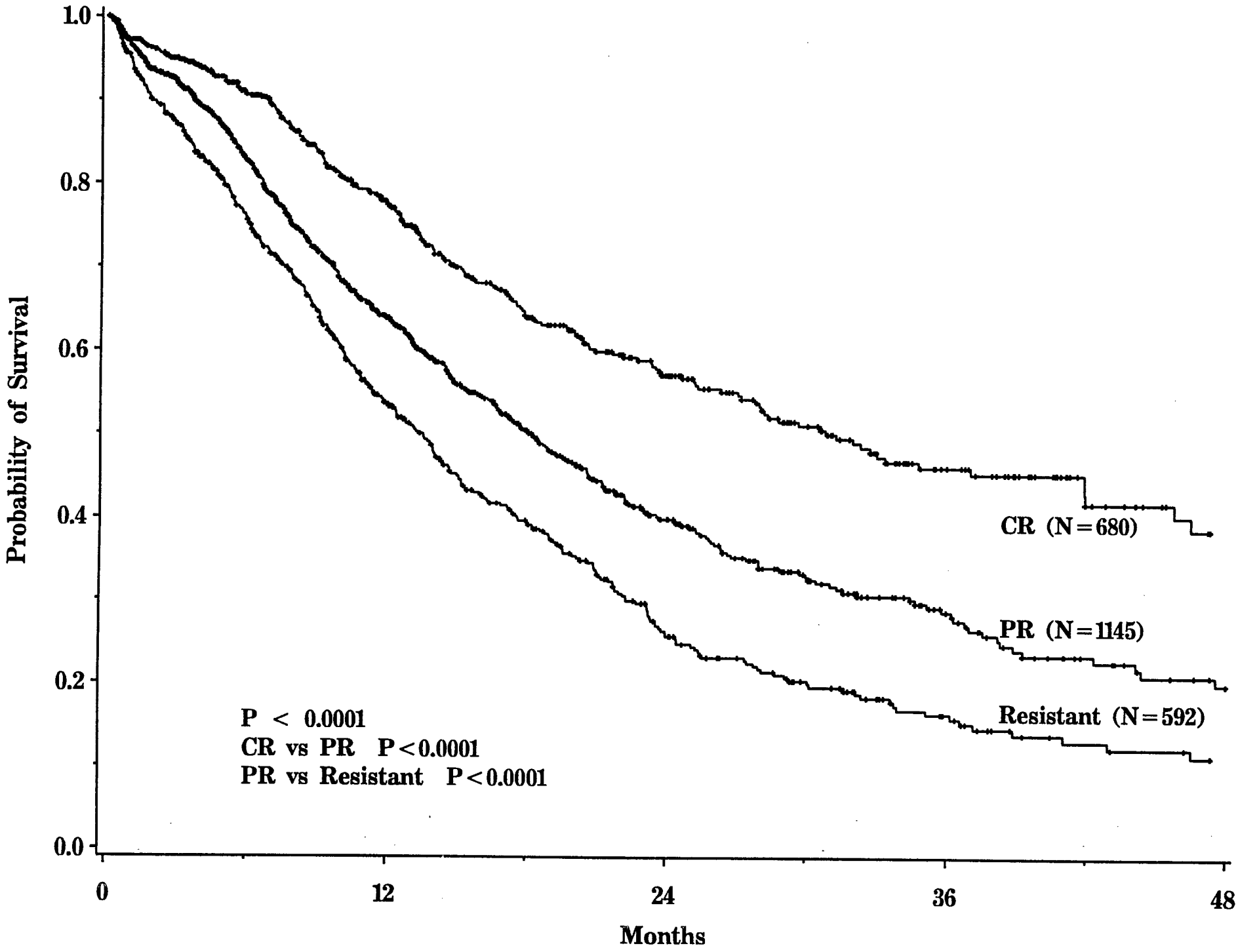


* Average number of transplants done yearly in each 2-year period


1.0
0.8
0.6
0.4
0.2
0.0
Probability of PFS
0
12
24
36
48
Months
Stage 2 (N=640)
Stage 3 (N=530)
Inflammatory (N=224)
Metastatic (N=2686)
P < 0.0001
Stage 2 vs 3 P=0.1
Stage 2 vs Inflammatory P<0.0001
Stage 3 vs Inflammatory P<0.0001
Primary vs Metastatic P<0.0001


1.0
0.8
0.6
0.4
0.2
0.0
Probability of Survival
Stage 2 (N=712)
Stage 3 (N=570)
Inflammatory (N=253)
Metastatic (N=3393)
P < 0.0001
Stage 2 vs 3 P=0.48
Stage 2 vs Inflammatory P<0.0001
Stage 3 vs Inflammatory P<0.001
Primary vs Metastatic P<0.0001
0
12
24
36
48
Months


1.0
0.8
0.6
0.4
0.2
0.0
Probability of PFS
0
12
24
36
48
Months
CR (N=587)
PR (N=943)
Resistant (N=500)
P < 0.0001
CR vs PR P<0.0001
PR vs Resistant P<0.0001


1.0
0.8
0.6
0.4
0.2
0.0
Probability of Survival
0
12
24
36
48
Months
CR (N=680)
PR (N=1145)
Resistant (N=592)
P < 0.0001
CR vs PR P<0.0001
PR vs Resistant P<0.0001

Autologous Blood & Marrow Transplant Registry–North America

ABMTR NEWSLETTER

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The IBMTR/ABMTR Statistical Center introduces a new logo. The new look reflects the cooperation between the IBMTR & ABMTR and our optimism for continuing progress in blood and marrow transplantation.

Contents:

The ABMTR Newsletter is funded by an educational grant from Bristol-Myers Oncology.

MEDICAL COLLEGE OF WISCONSIN

ABMTR INITIATES STUDY OF AUTOTRANSPLANTS FOR ADVANCED OVARIAN CANCER

By Patrick J. Stiff, MD
Loyola University Medical Center, Maywood, Illinois

Despite recent improvements in conventional therapy of advanced ovarian carcinoma, the mortality rate remains 65% at 5 years and few women are cured[1-4]. Although initial response rates are high, drug resistance develops rapidly. Response rates with conventional salvage therapy are only 10–40% with responses lasting an average of 6 months.

Dose Intensity and Ovarian Cancer

Considerable data on dose-intensity in ovarian cancer treatment suggest that high-dose therapy may improve outcome[5-7]. *In vitro* studies demonstrate a favorable dose-response relationship for platinum, other alkylating agents and mitoxantrone, and additive or synergistic cytotoxicity with drug combinations[8-12]. Early transplant trials indicate that intensifying platinum-based chemotherapy to doses to approximately 5 times conventional levels increases response rates[13-15]. Patterns of response appear similar to those observed with high-dose therapy for lymphoma, testicular cancer and, possibly, breast cancer.

Relapsed/Refractory Ovarian Cancer

Early autotransplant trials usually included patients failing 2 prior regimens, with platinum-resistance (tumor progression during or within 6 months of achieving remission with platinum-based therapy). Responses varied from 55-75%, with substantial numbers of clinical complete remissions. Remission durations were short, usually 5-7 months. However, 10-15% of women had long-term remissions suggesting the possibility of cure.

(Continued on page 4)

SPECIAL ISSUE
REPORT ON STATE OF THE ART IN BLOOD AND MARROW TRANSPLANTATION WITH GUIDE TO IBMTR/ABMTR SUMMARY SLIDES
(see pages 6-12)

SCIENCE, SUNSHINE AND SCOTTSDALE ON THE AGENDA FOR 1997 ANNUAL IBMTR/ABMTR PARTICIPANTS' MEETING

By D'Etta Waldoch Koser, CMP, Associate Director, International Programs, IBMTR/ABMTR

The IBMTR/ABMTR Annual Meeting is scheduled for February 22-25 at the Radisson Resort Scottsdale. A full program of Scientific Sessions addressing the basic and clinical science of blood and marrow transplantation, Working Committee meetings and Data Management training is planned. CME credits are available.

- **Deadline for abstract submission extended to December 15.** Abstract Forms are available through the Statistical Center. $500 will be awarded to the abstract using the most innovative techniques for clinical research, with special attention given to studies benefitting from use of Registry data. Poster Sessions will be combined with a light dinner buffet each evening.
- **Housing is limited**; fax your Room Reservation Form to the Radisson Resort Scottsdale *today* to take advantage of special discounted guest room rates during peak season.
- Watch for "Provisional Program Update." Enclosed in that mailing are Northwest Airlines "Association Dollars Off Certificates" for discounted airfares for IBMTR/ABMTR meeting participants (some restrictions apply).

(Continued on page 14)

Message from the Scientific Advisory Committee Chair

James O. Armitage, MD, Chair, Scientific Advisory Committee

New ABMTR Studies Evaluate Growing Use of Autologous Transplantation

The Autologous Blood & Marrow Transplant Registry – North America (ABMTR) continues to grow. Currently, 188 participating centers in the United States, Canada, Mexico and South America provide data to the Registry. More than 100 physicians from these centers volunteer their time to serve on one or more ABMTR Working Committees, to plan and conduct studies using these data.

ABMTR centers registered about 7,000 new patients in 1995. The total number of transplants available for study exceeds 23,000. The distribution of diseases treated by those transplants is shown below.

Approximately two-thirds of transplants were for lymphoma (Hodgkin or non-Hodgkin) or breast cancer. However, more than 400 transplants each for neuroblastoma, ovarian cancer and testicular cancer were registered. Additionally, over 2,000 transplants for acute leukemia and over 1,000 for multiple myeloma are available for study. The Registry provides a unique resource for studying the impact of this complicated therapy on the management of patients with these disorders.

This issue of the *Newsletter* focuses on research being done in the use of high-dose therapy and transplantation to manage patients with ovarian cancer. However, this is just one of numerous ongoing studies that are possible only because of the participation of physicians and their transplant teams.

On behalf of the Registry, I want to express thanks to all those whose efforts are making this project a success.

Distribution of autotransplants performed beween 1989 and 1995, registered with the ABMTR by 188 centers in North and South America

Disease	Numbers, %
Breast cancer	7646 (33)
Non-Hodgkin lymphoma	5789 (25)
Hodgkin lymphoma	2992 (13)
Acute myelogenous leukemia	1965 (9)
Acute lymphoblastic leukemia	511 (2)
Chronic myelogenous leukemia	205 (1)
Multiple myeloma	1192 (5)
Neuroblastoma	579 (3)
Ovarian cancer	440 (2)
Testicular cancer	406 (2)
Brain tumor	272 (1)
Lung cancer	129 (<1)
Bone sarcoma	118 (<1)
Other cancer	813 (3)
Total	23,057

photo for position only

ABMTR Advisory Committee Chair, James O. Armitage, MD, is Professor and Chairman, Department of Medicine, University of Nebraska Medical Center, Omaha.
Dr. Armitage is also current President of the American Society for Clinical Oncology.

Five IBMTR/ABMTR Studies to be Presented at the American Society of Hematology Meetings in December

The IBMTR/ABMTR Statistical Center is coordinating more than 50 transplant-related studies, addressing a wide range of issues. Current projects include comparison of unrelated donor and autologous transplants for leukemia, determining risk factors for second cancers after allogeneic and autologous transplants, and identifying prognostic factors in autotransplants for breast cancer, among many others. These studies are possible because of data contributed by hundreds of transplant centers, 20 years of statistical expertise in analyzing transplant data and active involvement of investigators from IBMTR and ABMTR institutions.

IBMTR/ABMTR studies to be presented at the annual meeting of the American Society of Hematology (ASH), December 6-10, 1996 include:

Effect of Prior Interferon Therapy on Outcome of HLA-Identical Sibling Bone Marrow Transplant for Chronic Myelogenous Leukemia (CML) in First Chronic Phase; to be presented by Mary M. Horowitz (platform session). This study of 882 transplants for CML indicates that treatment with α-interferon pretransplant does not adversely affect outcome of HLA-identical sibling transplants. Analysis of additional data regarding pretransplant interferon dose and response is in progress and will be available in early December.

Solid Cancers after Bone Marrow Transplantation; to be presented by Rochelle E. Curtis (platform session). This study was done in collaboration with the Fred Hutchinson Cancer Center and the Radiation Epidemiology Branch of the National Cancer Institute. It found that bone marrow transplant recipients have an increased risk of developing solid cancers at specific sites. A trend toward increasing risk with time posttransplant as well as greater risk among younger patients underscores the need for lifelong surveillance of transplant recipients.

Long-term Survival and Analysis of Late Causes of Death after Allogeneic Bone Marrow Transplantation; to be presented by Gérard Socié (platform session). Patient, disease, and transplant characteristics were analyzed for their association with late death in 5,773 patients alive and disease-free $\geq$2 years posttransplant. The data suggest that graft-versus-host disease (GVHD) and relapse contribute to late as well as early posttransplant mortality and suggest the need for long-term follow-up of transplant recipients.

Effects of G- and GM-CSF on Outcomes Following HLA-Identical Sibling Bone Marrow Transplants for Early Leukemia; to be presented by Kerry Atkinson (poster session). The study analyzed patients receiving HLA-identical sibling bone marrow transplants for acute leukemia in complete remission and CML in first chronic phase. Preliminary analysis comparing patients receiving G- or GM-CSF with patients not receiving growth factors showed shorter time to neutrophil recovery with growth factors. There was no increase in relapse risk in any disease. Acute GVHD was not increased but there was increased risk of chronic GVHD in older patients receiving G- or GM-CSF.

A Decision Analysis of Unrelated Donor Transplantation for CML; to be presented by Stephanie J. Lee (platform session). This study uses data from the IBMTR and the National Marrow Donor Program, analyzed by Dr. Stephanie Lee (Dana-Farber Cancer Institute, Boston). Timing of unrelated transplants for CML in chronic phase was studied using a Markov model, incorporating the competing risks of death from CML and bone marrow transplantation, risks of chronic GVHD and adjustments for quality of life posttrans-plant and risk aversion. The study found a benefit of early transplantation that was greatest for younger persons, but evident even for patients >40 years of age.

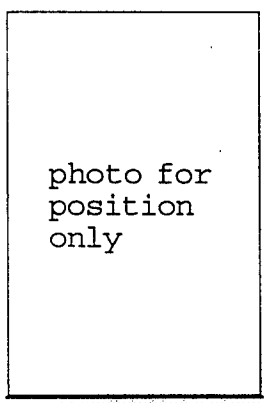
An important new area of study for the ABMTR is highlighted in this *Newsletter*: autotransplants for ovarian cancer. Patrick Stiff, Chair of the Ovarian Working Committee, reviews recent studies suggesting a role for high-dose therapy in advanced ovarian cancer (cover story). A short questionnaire was recently distributed to obtain additional data on women with ovarian cancer registered with the ABMTR. This study will provide important information on posttrans-plant outcomes and prognostic factors in a large number of women. We urge your participation.

Another important function of the Statistical Center is to provide yearly overviews of transplant outcomes. This issue of the *Newsletter* provides an interpretation guide for our **1996 Summary Slides on State-of-the-Art in Blood and Marrow Transplantation**. The slides will be sent to all IBMTR/ABMTR Participating Teams and to IBMTR/ABMTR Corporate Members in January.

Thank you for your participation in the research programs of the IBMTR and ABMTR. With your collaboration, we are able to continue our important work to improve the success of blood and marrow transplantation.

Message from the Scientific Director

Mary M. Horowitz, MD, MS
Scientific Director



Mary M. Horowitz, MD, MS is Scientific Director of the IBMTR/ABMTR and Professor of Medicine at the Medical College of Wisconsin

A survey of U.S. programs with active autotransplant protocols for ovarian carcinoma was conducted in 1992[16]. Eleven centers reported 153 patients of whom 146 received transplants for relapsed or refractory disease. Among 61 women with platinum-resistant tumors, 51% had partial and 34%, complete responses. Among 37 with platinum-sensitive disease, 14% had partial and 73%, complete responses. Median progression free survival (PFS) in the entire group was 6 months. 14% of women were disease-free 1 year after treatment.

A trial at Loyola University (Chicago) also found an association between platinum-sensitivity and transplant outcome[17]. Among 30 women receiving high-dose mitoxantrone, carboplatinum and cyclophosphamide, median PFS was 10.1 months for 10 with platinum-sensitive disease versus 5.1 months for 20 with platinum-resistance (p=.03). 80% of those with platinum-sensitive disease were alive 18 months posttransplant. A recent (unpublished) update of 34 patients with platinum-sensitive disease <1 cm in diameter at time of transplant showed median PFS of 19 months and overall survival of 30 months. These data, when compared to historical results in relapsed ovarian cancer, suggest that autotransplants may be superior to conventional therapy for patients with platinum-sensitive tumors, though one must be cautious in interpreting single-arm studies of patients referred for transplant.

Persistent Disease at Second-Look Laparotomy

Several pilot studies of autotransplants in women with persistent ovarian cancer at second-look laparotomy are reported. Dauplat et al. described 14 such patients (12 with microscopic disease) receiving a single course of high-dose melphalan[18]. Three-year PFS and survival were 33% and 64%. A recently published update demonstrated median PFS of 27 months in 31 women[19]. Of 19 women reported by Viens et al., 3 of 10 with disease <2 cm in diameter and 6 of 9 with pathologic complete remissions were alive and disease-free at a median follow-up of 22 months after high-dose therapy[20]. Among 87 women receiving autotransplants after second-look laparotomy reported by Extra et al., median survival after transplant was 47 months[21]. Sixty-five (76%) of these had suboptimal stage III and IV disease, a group with, historically, only about 2 years survival after conventional-dose platinum and cyclophosphamide. These data suggested better response with autotransplants and also demonstrated its safety. The fatal toxicity rate was only 1.1%.

The Southwest Oncology Group is currently conducting a randomized trial comparing two transplant regimens for patients with <3 cm disease at second-look laparotomy to verify safety and efficacy of autotransplants in this setting.

Initial Management of Ovarian Cancer

Several studies report results of high-dose chemotherapy after induction chemotherapy for advanced ovarian cancer. Benedetti-Panici et al. treated 35 women presenting with Stage III or IV disease with 2-4 cycles of standard chemotherapy followed by either high-dose cisplatinum, carboplatinum and etoposide or carboplatinum, etoposide and melphalan stem cell rescue[22]. Among 24 women completing all therapy, 10 (42%) had a pathologic complete response. Seven remain in remission more than 3 years posttransplant.

To facilitate the ABMTR study of ovarian cancer, a request for additional data was recently sent to participating transplant centers. We encourage you to submit this brief supplemental form as quickly as possible. Additionally, a new form is being developed to prospectively capture data on autotransplants for ovarian cancer. Analyses of these data will be important for designing future clinical trials and improving outcome of transplants for ovarian cancer.

Fennelly et al. treated 16 patients (10 suboptimally debulked) with high-dose cyclophosphamide and Taxol with cytokine support only for 2 cycles followed by 4 courses of carboplatinum and cyclophosphamide and blood stem cell rescue[23]. Five (38%) women had a negative second-look laparotomy. This may or may not be better than achievable with Taxol and cisplatinum at conventional doses.

The Next Step

While these data are encouraging, the true role of autotransplants in management of advanced ovarian cancer is still uncertain. Randomized trials are needed. Under the auspices of the National Cancer Institute (NCI), one such trial will soon start in the U.S. Cooperative Groups (GOG164). In this study, after initial surgery, women with Stage III ovarian cancer will receive 4-6 cycles of a platinum-based regimen followed by second-look laparotomy. Those with low tumor burden (microscopic disease for optimal Stage III, <1 cm for suboptimal Stage III) will be randomized to either six cycles of carboplatin and Taxol or a single cycle of high-dose carboplatin, mitoxantrone and cyclophosphamide[17] and a blood stem cell transplant.

Role of the ABMTR

Little is known about which patients are most likely to benefit from high-dose therapy. The influence of timing, platinum-sensitivity, tumor bulk, histology and grade, high-dose chemotherapy regimen, and multiple cycles of moderate-dose chemotherapy are all important issues. Neither the currently planned randomized nor single institution Phase II trials can address all of these satisfactorily. The ABMTR, by accumulating data on hundreds of autotransplants for ovarian cancer, is uniquely suited to these issues. **Thanks to a generous educational grant from Amgen, Inc., an ABMTR study of autotransplants for ovarian cancer was recently initiated.** This study will define the survival rate after autotransplants in a large group of women, identify prognostic factors for transplant outcome and suggest the most successful transplant strategies.

To facilitate the ABMTR study of ovarian cancer, a request for additional data was recently sent to participating transplant centers. We encourage you to submit this brief supplemental form as quickly as possible. Additionally, a new form is being developed to prospectively capture data on autotransplants for ovarian cancer. Analyses of these data will be important for designing future clinical trials and improving outcome of autotransplants for ovarian cancer.

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(Continued on next page)

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ABMTR MEMBER PROFILE: PATRICK J. STIFF, MD

photo for position only

Patrick J. Stiff, MD is Associate Professor of Medicine and Director of the Bone Marrow Transplant Program at the Loyola University Stritch School of Medicine in Maywood, Illinois. Dr. Stiff is a member of the ABMTR Scientific Advisory Committee and chair of the Ovarian Cancer Committee. He is nationally recognized for his pioneering work in autotransplants for ovarian cancer.

After receiving his medical degree in 1975 from Loyola University, Dr. Stiff completed a fellowship in medical oncology at Memorial Sloan-Kettering Cancer Center in New York. In 1981, he was appointed Assistant Professor and Director of Bone Marrow Transplantation Services at Southern Illinois University School of Medicine in Springfield, Illinois where he was named Faculty Member of the Year in 1985. He joined the Department of Hematology/Oncology at Loyola in 1986.

Dr. Stiff is a member of many scientific and medical organizations. Among these are the Gynecologic Oncology Executive Committee, Leukemia Committee and Lymphoma Committee of the Southwest Oncology Group and Board of Directors of the International Society for Hematotherapy and Graft Engineering. Dr. Stiff is also a member of the State of Illinois Medical Advisory Committee, serving on the Subcommittee on Transplantation. Dr. Stiff has authored or co-authored over 30 articles in scientific journals as well as many book chapters.

Through Dr. Stiff's efforts the ABMTR has developed a data collection form for ovarian cancer and initiated the first ABMTR analysis of autotransplants in ovarian cancer.

1996 SUMMARY SLIDES SHOW CURRENT USE AND OUTCOME OF BLOOD AND MARROW TRANSPLANTATION

By Philip A. Rowlings, MD, MS
IBMTR/ABMTR Assistant Scientific Director

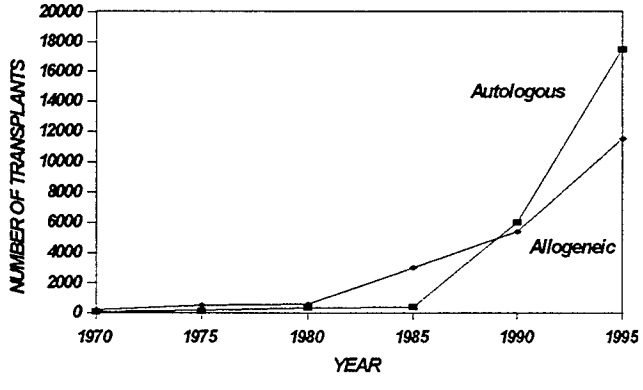
Since 1972 the IBMTR has collected data from over 300 transplant centers, worldwide. The IBMTR database includes information for about 40% of allogeneic bone marrow transplants done between 1970 and 1995. In 1991, the ABMTR began collecting data on autotransplants from centers in North and South America. More than 180 autotransplant centers now contribute data to the ABMTR. The ABMTR database includes information for about 50% of autotransplants done in North America between 1989 and 1995.

Using these data, the Statistical Center periodically prepares and distributes slides summarizing current use and outcome of allogeneic and autologous hematopoietic stem cell transplants. **This year's Summary Slides, made possible by a generous educational grant from Bristol-Myers Oncology, are described below.**

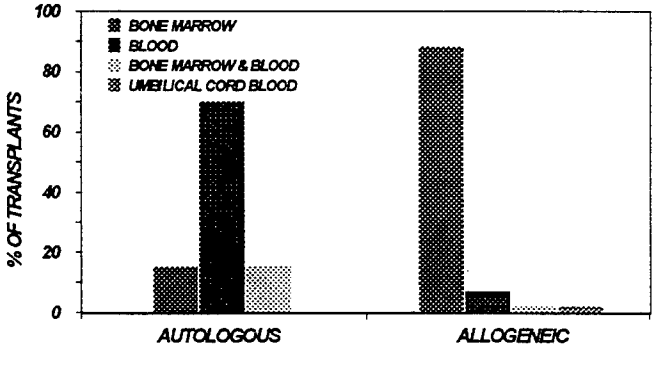
Slide 1: Use of blood and marrow transplants continues to increase. We estimate 12,000 allogeneic and 18,000 autologous transplants were done in 1995, worldwide.

Slide 2: Most autotransplants use hematopoietic progenitor cells collected from blood. Fewer than 20% are done with bone marrow alone. In contrast, over 90% of allografts use bone marrow. Despite recent interest in collecting allogeneic cells from peripheral blood or umbilical cord blood, few such transplants have yet been done.

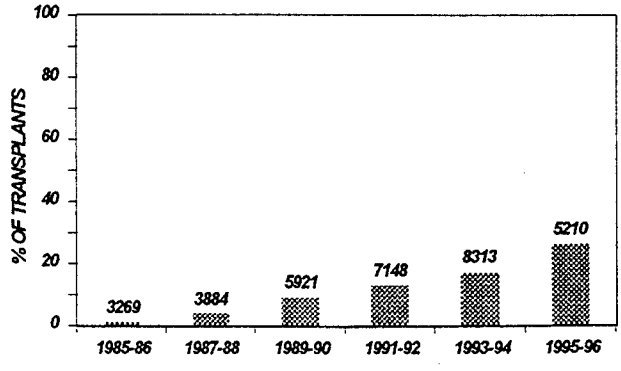
Slide 3: Most allogeneic transplants are from HLA-identical sibling donors. However, only about 30% of transplant candidates have such a donor. Increasing availability of HLA-typed volunteers through large national and international registries has enabled increasing use of unrelated donors for bone marrow transplants. Transplants



Slide 1. *Annual Number of Blood and Marrow Transplants Worldwide, 1970-1995*



Slide 2. *Stem Cell Sources, 1995*



Slide 3. *Percent of Allogeneic Transplants from Unrelated Donors*

from unrelated donors now account for about 25% of allogeneic transplants.

Slide 4: The most common indications for allogeneic and autologous transplants differ. Among cases reported to the IBMTR/ABMTR, 74% of allogeneic transplants are for leukemia or preleukemia: 22% for chronic myelogenous leukemia (CML), 23% for acute myelogenous leukemia (AML), 19% for acute lymphoblastic leukemia (ALL), 7% for myelodysplastic syndromes and 3% for other leukemias. Ten percent are for other cancers including non-Hodgkin lymphoma (6%), multiple myeloma (3%), and Hodgkin disease (<1%). The remainder are for aplastic anemia (7%), immune deficiencies (2%), inherited disorders of metabolism (1%) and other non-malignant disorders (6%). Autotransplants are used to treat cancer. The most common indications for autotransplants in North America in 1995 were breast cancer (42%), non-Hodgkin lymphoma (23%), Hodgkin disease (9%), multiple myeloma (8%), AML (6%), ovarian cancer (2%), ALL (1%), CML (1%), with 8% for a variety of other cancers. The most striking recent change in autotransplant use is the dramatic increase in autotransplants for breast cancer. In 1989, about 15% of autotransplants in North America were for breast cancer while in 1995, over 40% were for breast cancer.

Slide 5: 100-day mortality is often used as a gauge of procedure-related toxicity. Allogeneic transplants are associated with high risks of graft-versus-host disease (GVHD), infections and liver toxicity, resulting in relatively high early mortality. Among HLA-identical transplants done in 1995 and reported to the IBMTR, 100-day mortality rates range from about 10% for persons with acute leukemia in first remission to almost 40% for those with advanced leukemia. Progressive leukemia

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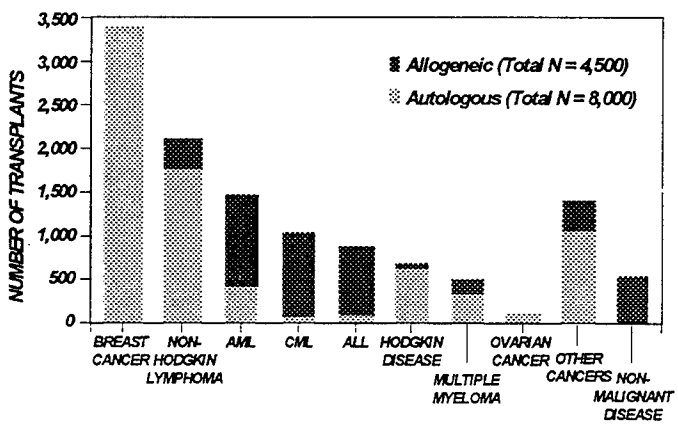
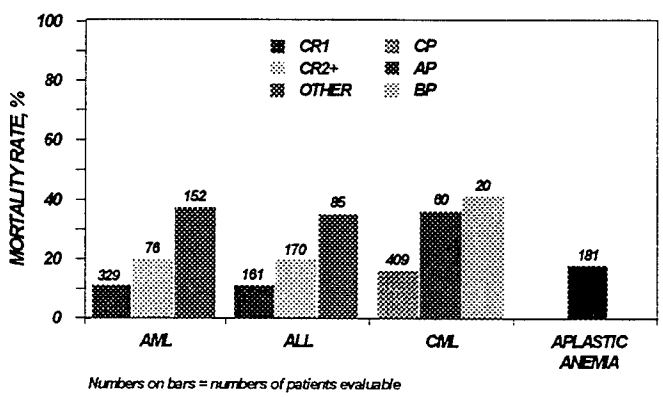
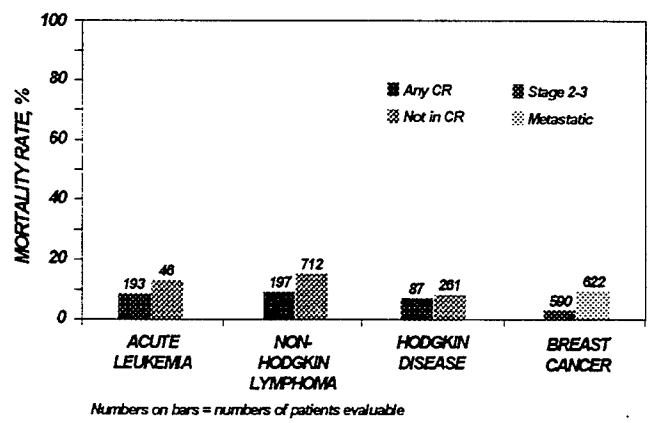


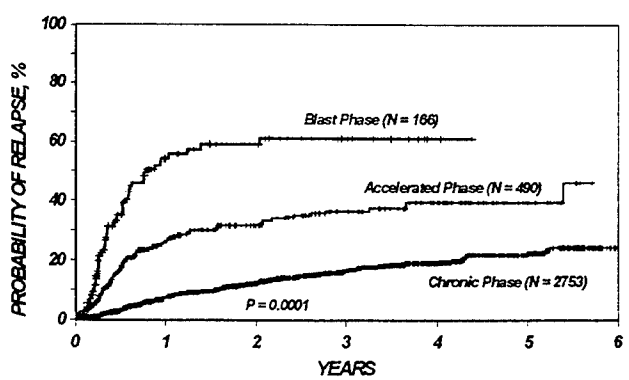
Slide 4. *Indications for Blood and Marrow Transplantation in North America, 1995*



Slide 5. *100-Day Mortality after HLA-identical Sibling Transplants, 1995*



Slide 6. *100-Day Mortality after Autotransplants, 1995*



Slide 7. *Probability of Relapse after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995*

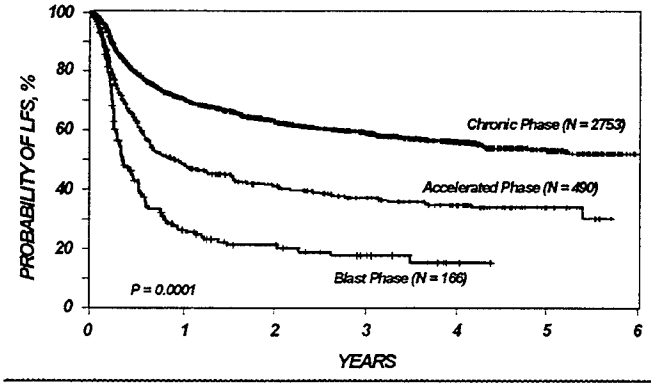
contributes to the early mortality rates among patients transplanted with advanced disease.

Slide 6: Early mortality is generally lower after auto- than allotransplants. Among autotransplants done in 1995 and reported to the ABMTR, 100-day mortality ranges from <5% in women with Stage 2-3 breast cancer to about 15% in persons with advanced lymphoma.

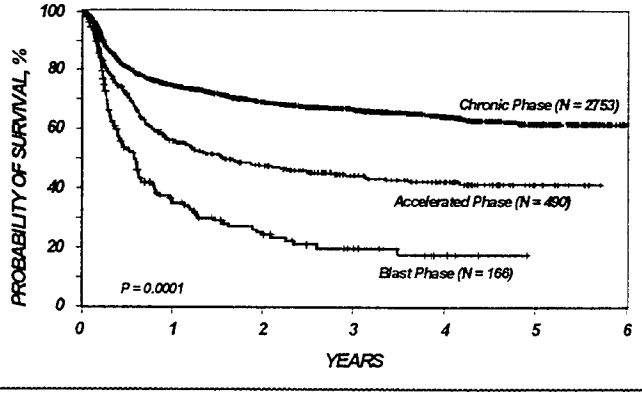
Slides 7, 8: CML is the most frequent indication for allogeneic bone marrow transplantation. Among 3,409 recipients of HLA-identical sibling transplants done between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse (95% confidence interval) were 16 ± 2% for 2,753 transplants done in first chronic phase, 36 ± 6% for 490 in accelerated phase, and 61 ± 11% for 166 in blast phase. 3-year probabilities of leukemia-free survival (LFS) were 59 ± 2%, 37 ± 5% and 17 ± 7%, respectively.

Slide 9: Persons relapsing after an HLA-identical sibling transplant for CML often survive for long intervals with conventional treatment. Many achieve durable hematologic and cytogenetic remissions with infusion of donor lymphocytes. Consequently, 3-year survival rates after transplants are somewhat higher than LFS rates: 66 ± 2% in chronic phase, 44 ± 5% in accelerated phase, and 19 ± 7% in blast phase.

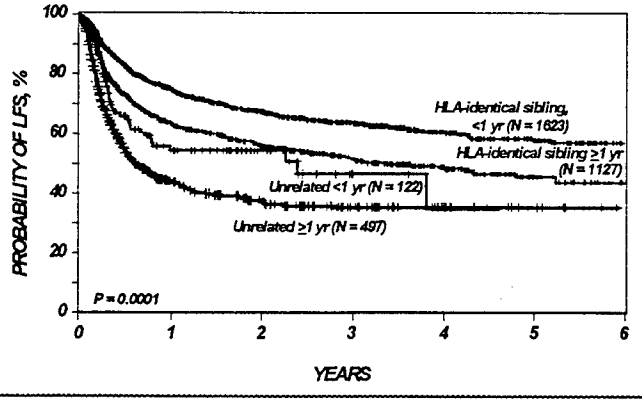
Slide 10: Only about 30% of persons with CML have an HLA-identical sibling donor. Unrelated donor transplants can cure CML but are associated with higher risks of GVHD and transplant-related mortality. Additionally, unrelated donor transplants are often delayed because of the time required to identify a donor and reluctance to risk the high transplant-related mortality. Delaying transplantation may adversely



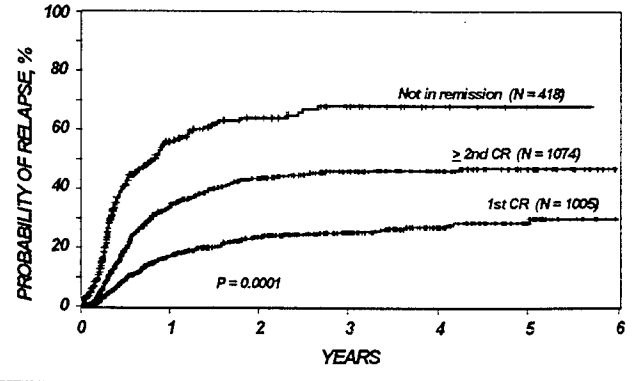
Slide 8. *Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995*



Slide 9. *Probability of Survival after HLA-identical Sibling BMT for Chronic Myelogenous Leukemia, 1989-1995*



Slide 10. *Probability of LFS after BMT for Chronic Myelogenous Leukemia in Chronic Phase, by Donor Type and Time to Transplant*



Slide 11. *Probability of Relapse after HLA-identical Sibling BMT for Acute Lymphoblastic Leukemia 1989-1995*

affect outcome. Slide 10 shows LFS after 1,623 HLA-identical sibling transplants done <1 year after diagnosis of CML (64 ± 3% at 3 years), 1,127 HLA-identical sibling transplants done a year or more after diagnosis (51 ± 3%), 122 unrelated donor transplants done <1 year after diagnosis (47 ± 13%), and 497 unrelated donor transplants done a year or more after diagnosis (35 ± 5%). Outcome of unrelated donor transplantation may be affected by factors other than interval between diagnosis and transplant such as donor-recipient histocompatibility, recipient age and others.

Slides 11, 12: Most patients with ALL are cured with conventional chemotherapy. Consequently, bone marrow transplants are generally reserved for patients failing conventional therapy, i.e., in relapse or second or subsequent remission, or patients in first remission with prognostic factors predicting a high risk of failure with conventional therapy. The most frequent indications for transplants in first remission are older age, high leukocyte count at diagnosis, Ph^1 and other chromosome abnormalities and difficulty obtaining a first remission. Among 2,497 recipients of HLA-identical sibling transplants between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse were 25 ± 4% for 1,005 transplants done in first remission, 46 ± 4% for 1,074 in second or subsequent remission, and 68 ± 7% for 418 done in relapse. 3-year probabilities of LFS were 54 ± 4%, 40 ± 13% and 20 ± 5%, respectively.

Slides 13, 14: Among 357 recipients of autotransplants for ALL done between 1989 and 1995, reported to the ABMTR, 3-year probabilities of relapse were 49 ± 14% for 102 transplants done in first remission, 70 ± 7% for 228 done in second or subsequent remission, and 76 ± 24% for 27 done in relapse. 3-year probabilities of LFS were 43 ± 12%, 25 ± 6% and 17 ± 17%, respectively.

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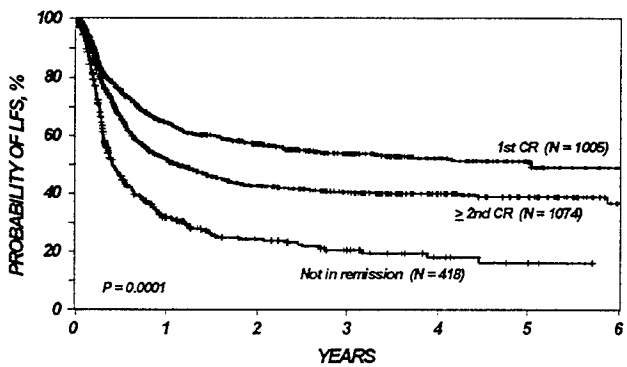
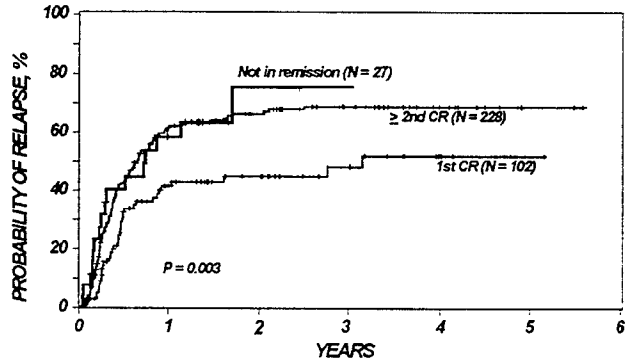
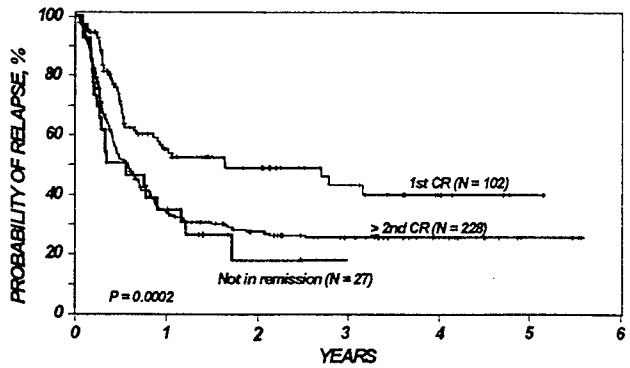


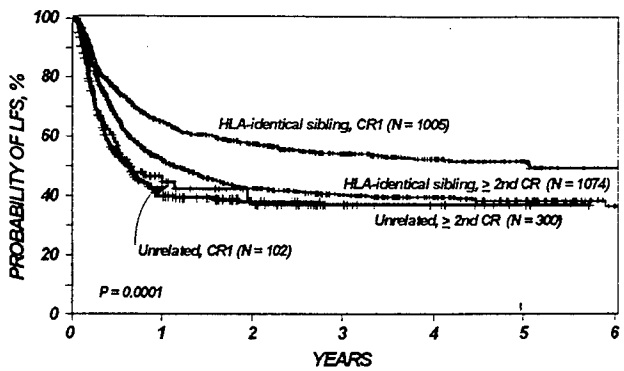
Slide 12. *Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Acute Lymphoblastic Leukemia, 1989-1995*



Slide 13. *Probability of Relapse after Autotransplants for Acute Lymphoblastic Leukemia, 1989-1995*



Slide 14. *Probability of Leukemia-free Survival after Autotransplants for Acute Lymphoblastic Leukemia, 1989-1995*



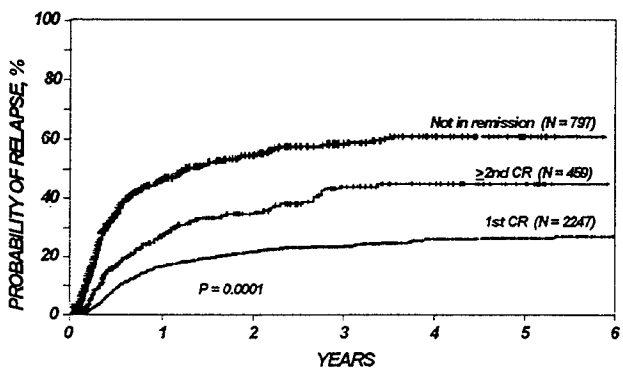
Slide 15. *Probability of Leukemia-free Survival after Allogeneic BMT for Acute Lymphoblastic Leukemia, 1989-1995*

Slide 15: Although associated with higher transplant-related mortality, unrelated donor transplants may be considered for patients with ALL unlikely to be cured with chemotherapy. Among 102 recipients of unrelated donor transplants for ALL in first remission reported to the IBMTR, 3-year LFS was 37 ± 14%; among 300 receiving unrelated donor transplants in second or subsequent remission, LFS was 36 ± 6%. Among patients transplanted in second remission, there was no difference in LFS between HLA-identical sibling and unrelated donor transplants, since higher GVHD rates were offset by lower relapse rates after unrelated donor transplants.

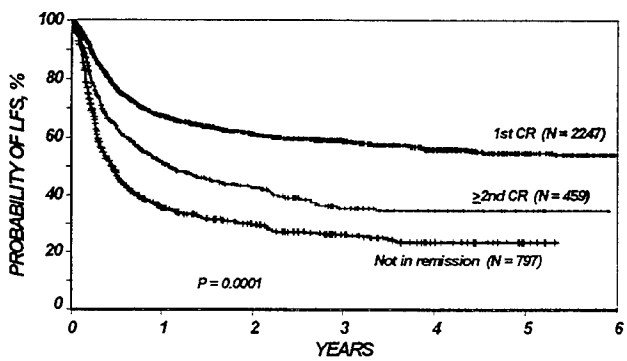
Slides 16, 17: As in ALL, results of HLA-identical sibling transplants for AML correlate with remission state. Among 3,503 recipients of HLA-identical sibling transplants done between 1989 and 1995, reported to the IBMTR, 3-year probabilities of relapse were 24 ± 2% for 2,247 transplants done in first remission, 45 ± 8% for 459 in second or subsequent remission and 57 ± 5% for 979 done in relapse. 3-year probabilities of LFS were 59 ± 2%, 35 ± 5% and 26 ± 4%, respectively.

Slides 18, 19: Among recipients of auto-transplants for AML between 1989 and 1995, reported to the ABMTR, 3-year probabilities of relapse were 44 ± 4% for 858 transplants done in first remission, 56 ± 6% for 401 in second or subsequent remission and 83 ± 8% for 144 done in relapse. 3-year probabilities of LFS were 50 ± 4%, 38 ± 5% and 12 ± 7%, respectively.

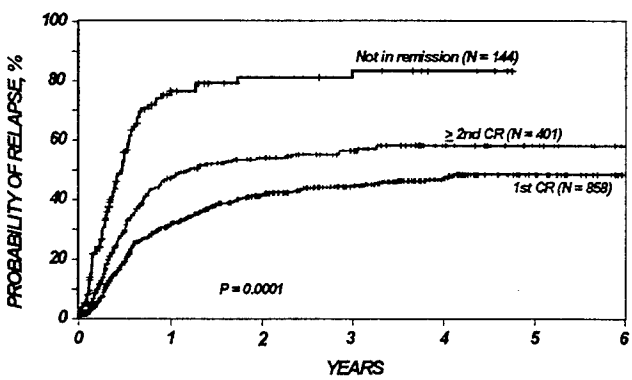
Slide 20: As in ALL, unrelated donor transplants may be considered for some patients with AML lacking an HLA-identical sibling donor. Among 208 patients receiving unrelated donor transplants for AML between 1989 and 1995, reported to the IBMTR, the 3-year probability of LFS was 57 ± 13% for 87 receiving a transplant in first remission and 25 ± 12% for 121



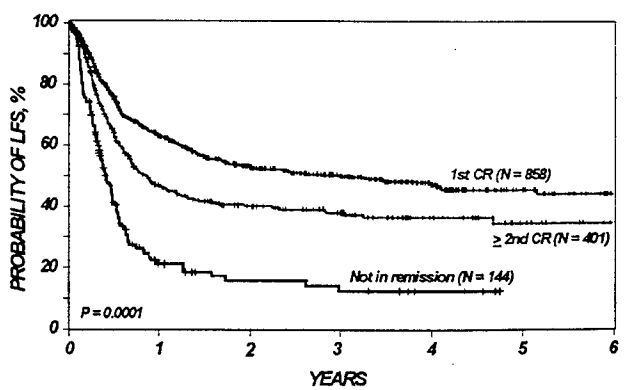
Slide 16. *Probability of Relapse after HLA-identical Sibling BMT for Acute Myelogenous Leukemia, 1989-1995*



Slide 17. *Probability of Leukemia-free Survival after HLA-identical Sibling BMT for Acute Myelogenous Leukemia, 1989-1995*



Slide 18. *Probability of Relapse after Autotransplants for Acute Myelogenous Leukemia, 1989-1995*



Slide 19. *Probability of Leukemia-free Survival after Autotransplants for Acute Myelogenous Leukemia, 1989-1995*

receiving a transplant in second or subsequent remission.

Slide 21: Bone marrow transplantation is the treatment of choice for young patients with aplastic anemia who have an HLA-identical sibling. 3-year probabilities of survival after 1,477 HLA-identical sibling transplants between 1989 and 1995, reported to the IBMTR, were 73 ± 4% for patients <20 years of age and 61 ± 5% for those older. Results were not as good in 200 recipients of unrelated donor transplants: 41 ± 10% in 136 patients <20 years and 40 ± 13% in 64 older patients.

Slide 22: Most patients with Hodgkin disease are cured with conventional chemotherapy. However, for the 20-30% failing conventional therapy, auto-transplants are effective salvage therapy. Among 993 autotransplants between 1989 and 1995, reported to the ABMTR, 3-year probabilities of survival were 86 ± 12% for 49 patients transplanted in first remission, 60 ± 6% for 463 transplanted in first relapse and 76 ± 8% for 224 transplanted in second or subsequent remission and 49 ± 9% for 257 patients never in remission.

Slide 23, 24: Autotransplants are also commonly used for non-Hodgkin lymphoma. Among 407 patients receiving auto-transplants for low-grade lymphoma, 3-year probabilities of survival were 83 ± 14% for 64 patients transplanted in first remission, 67 ± 11% for 159 in first relapse, 65 ± 16% for 64 in second remission and 52 ± 16% for 120 never achieving remission with standard chemotherapy. Among 1,413 patients receiving autotransplants for intermediate grade or immunoblastic lymphoma, 3-year probabilities of survival were 68 ± 10% for 143 patients in first remission, 45 ± 5% for 594 in first relapse, 60 ± 8% for 250 in second remission and 40 ± 7% for 426 never

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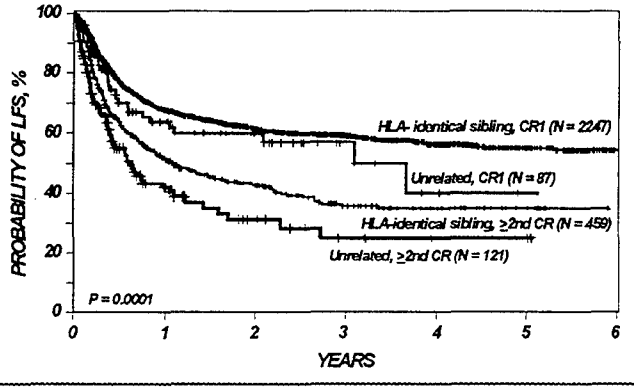
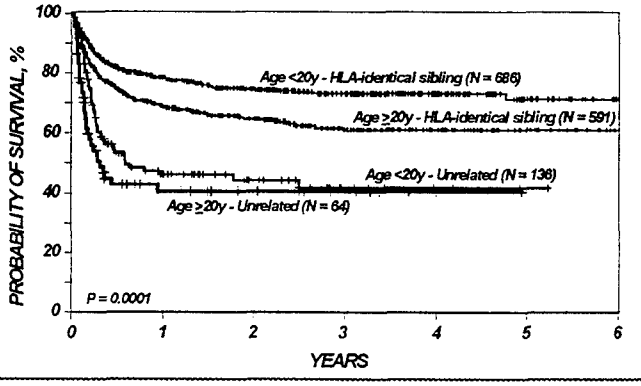
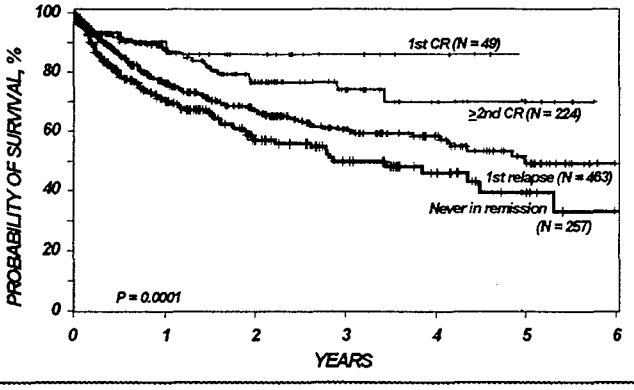


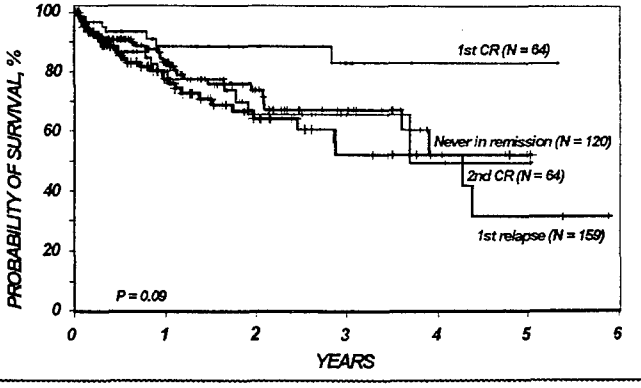
Slide 20. *Probability of Leukemia-free Survival after Allogeneic BMT for Acute Myelogenous Leukemia, 1989-1995*



Slide 21. *Probability of Survival after HLA-identical Sibling and Unrelated BMT for Severe Aplastic Anemia, 1989-1995*



Slide 22. *Probability of Survival after Autotransplants for Hodgkin Disease, 1989-1995*



Slide 23. *Probability of Survival after Autotransplants for Low-Grade Non-Hodgkin Lymphoma, 1989-1995*

achieving remission with conventional chemotherapy. Most failures after autotransplants for non-Hodgkin lymphoma are due to relapse.

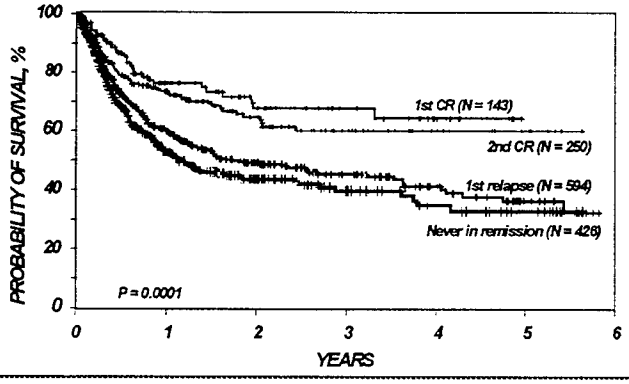
Slide 25, 26: Breast cancer is the most frequent indication for autotransplants in North America. Among 5,705 women receiving autotransplants for breast cancer between 1989 and 1995 and reported to the ABMTR, 3-year probabilities of survival were 74 ± 6% in 888 women with Stage 2 disease, 70 ± 7% in 749 women with Stage 3 disease, 51 ± 11% in 314 women with inflammatory breast cancer and 31 ± 2% in 3,754 women with metastatic breast cancer.

Outcome in metastatic breast cancer is significantly better for women achieving a complete response with conventional therapy prior to transplant. Among the 3,220 women transplanted for metastatic disease in whom pretransplant response to chemotherapy was known, 3-year survival was 45 ± 5% in 901 with a complete response, 27 ± 4% in 1,557 with a partial response and 17 ± 4% in 762 women with resistant disease.

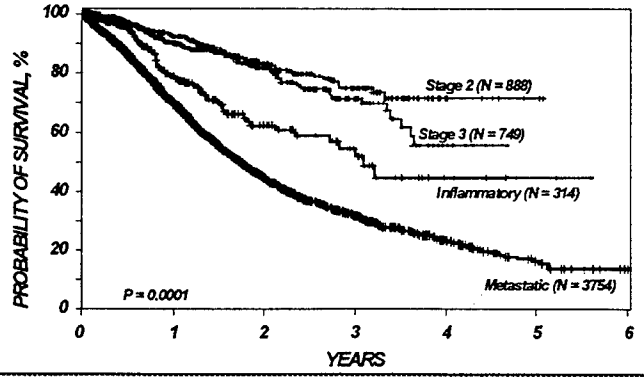
Two sets of slides will be sent to participating teams of the IBMTR/ABMTR free of charge. Teams may purchase additional sets for $50.00.

If your budget does not permit this purchase, limited educational grants are available through the Statistical Center.

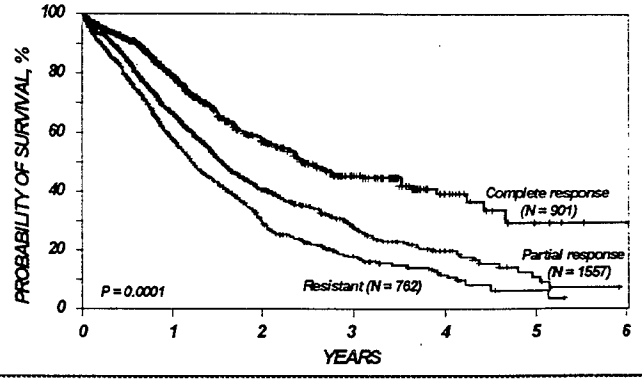
If you have any questions about our new slides, please call Melodee L. Nugent, MA at ☎(414) 456-8325.



Slide 24. *Probability of Survival after Autotransplants for Intermediate Grade or Immunoblastic Non-Hodgkin Lymphoma, 1989-1995*



Slide 25. *Probability of Survival after Autotransplants for Breast Cancer, 1989-1995*



Slide 26. *Probability of Survival after Autotransplants for Metastatic Breast Cancer by Pretransplant Chemosensitivity, 1989-1995*

STATISTICAL METHODS FOR ANALYZING TRANSPLANT OUTCOME

By
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Wisconsin

Transplant outcome depends on complex interactions among patient characteristics, disease biology and treatment. A statistical tool frequently used by the Statistical Center to study those interactions is regression analysis. Regression analyses examine the relationship between a set of factors (independent or explanatory variables) and an outcome (dependent or response variable). Explanatory variables may be patient and disease characteristics like age and disease stage and/or treatment strategies like conditioning regimen and growth factor use.

There are many techniques for regression analysis. The technique used for a specific study is determined by the outcome or response variable of interest. If the outcome is a continuous variable, e.g., days of hospitalization after high-dose therapy, linear regression is commonly used. Linear regression models consider the mean of the response variable as a linear function (sum) of a set of explanatory variables plus some measurement error. For example, a person's days in the hospital might be predicted by the sum of age, disease and growth factor use, each multiplied by an appropriate factor determined in the regression analysis.

For binary (yes/no) data (e.g., 100-day mortality), logistic regression is the most common approach. Logistic regression models the logarithm of the odds of an event occurring (yes response) as a linear function of the explanatory variables. The odds of an event occurring is the ratio of the probability of the event occurring divided by the probability of the event not occurring. When the independent variable is also binary, the logistic model also estimates the odds ratio for the independent variable. This gives a measure of how much more likely it is that an event will occur in an individual with a certain characteristic as compared to an individual without the characteristic. Logistic regression is available in many statistical packages. A good introductory book on this technique is Kleinbaum's *Logistic Regression: A Self Learning Text*, Springers Series on Statistics in the Health Sciences, 1994. Logistic regression techniques are also used to analyze matched-pairs data and analyze data where the response has more than two characteristics.

Most transplant studies focus on outcomes that involve time, e.g., time to engraftment, time to graft-versus-host disease (GVHD), time to disease recurrence, and time to death. The outcome measure has two aspects: whether or not the event occurs and the time at which it occurs. An important issue in these studies is that patients analyzed may be followed for different lengths of time (either because of entering the study at different times or loss to follow-up) or may die from another cause before the event occurs. These patients are *censored*. Whether they would have developed the event of interest with longer follow-up is unknown. For these situations, the technique most commonly used is *Cox* or *proportional hazards* regression.

Cox regression models the hazard rate of the time to occurrence of an event (hazard rate is the chance the event occurs at a given time for patients who have yet to experience the event). It assumes that for an individual with a given set of characteristics (explanatory variables), the hazard rate at any point in time can be obtained by multiplying a baseline hazard rate by the exponential of a linear function of the independent variables. It is called a proportional hazards model since individuals with distinct values of the independent covariates have hazard rates that are proportional at all points in time. The ratio of the hazard rates for such individuals is called the relative risk and gives a measure of how much more quickly individuals with one set of risk factors experience the event than individuals with some other set of risk factors. Cox regression is available in some of the standard statistical packages such as SAS and BMDP. It allows for the handling of censored data (data where some individuals do not experience the event) in a natural way. A good introductory reference on this techniques is the book by Kleinbaum on *Survival Analysis: A Self Learning Text*, Springers Series on Statistics in the Health Sciences, 1996.

Selection of the appropriate statistical model is crucial to avoid bias and maximize power to detect important relationships between explanatory and response variables. All models make some assumptions about these relationships (e.g., the assumption of proportionality for Cox models). Failure to check or meet these assumptions can produce misleading results. Though regression techniques are widely available in statistical packages, they should be used with guidance of persons with the statistical background to assure appropriate models are used correctly.

photo for position only

IBMTR/ABMTR Biostatisticians (left-right): Kathleen A. Sobocinski, MA; John P. Klein, PhD; Mei-Jie Zhang, PhD

RECENT SCIENTIFIC REPORTS FROM THE IBMTR/ABMTR

Gale RP, Horowitz MM, Rees JKH, Gray RG, Oken MM, Estey EH, Kim KM, Zhang MJ, Ash RC, Atkinson K, Champlin RE, Dicke KA, Gajewski JL, Goldman JM, Helbig W, Henslee-Downey PJ, Hinterberger W, Jacobsen N, Keating A, Klein JP, Marmont AM, Prentice HG, Reiffers J, Rimm AA, Rowlings PA, Sobocinski KA, Speck B, Wingard JR, Bortin MM. **Chemotherapy versus transplants for acute myelogenous leukemia in second remission.** Leukemia, 10:13-19, 1996.

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REPRINTS AVAILABLE ON REQUEST

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*Annual Meeting...**(continued from page 1)*

- Assistance with flights to Sky Harbor International Airport in Phoenix is available through Meetings & Incentives ☎ (414) 835-3553 ext.126 or (800) 776-3582 ext.126.
- Sky Harbor Airport is an easy 20 minute drive to the Radisson Resort Scottsdale. Special rental discounts available through Hertz—the official car rental company: ☎ (800) 654-2240; refer to CV#17584.

IBMTR/ABMTR Working Committee meetings are open to those interested in *actively* participating in ongoing and future Registry studies. All Working Committee members should plan to attend.

Fifty $500 grants were recently awarded to persons registered for the Data Management Workshops on Saturday, February 22. Grant funds were provided by the US Department of the Army for teams submitting breast cancer data to the ABMTR. The Data Management Workshops are designed specifically for clinical research associates, data managers, nurses and others interested in data management. Fundamentals of Registry data management and special topics related to clinical research will be covered.

StemCell Technologies, Inc. will offer "hands-on" training for StemSoft data entry software on Sunday, February 23. Call Violet Molnar in Vancouver, BC at ☎ (604) 877-0713 to register. The fee for this additional session is US $300.

All members of IBMTR and ABMTR-North America participating bone marrow transplant teams are encouraged to attend. We hope to have each team represented at the 1997 Meeting.

Detailed meeting brochures available, please contact: D'Etta Waldoch Koser, CMP, at the Statistical Center; ☎ **(414) 456-8377,** fax: **(414) 266-8471,** or email: **ibmtrdwk@hp04.biostat.mcw.edu**

FOUNDATION AND CORPORATE SUPPORT OF THE IBMTR/ABMTR

By Susan Ladwig, MA
Associate Director of Development, Statistical Center

All of us at the IBMTR/ABMTR Statistical Center thank the many contributors who have joined our international collaboration for research in blood and marrow transplantation. Private support for the Registries continues to be vitally important since federal grants cover only 60 percent of the Statistical Center's budget. We gratefully acknowledge the support of the Medical College of Wisconsin; the National Cancer Institute; the National Institute of Allergy and Infectious Disease; the National Heart, Lung and Blood Institute; the Department of Defense; and the generosity of the following foundations and corporations:

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Several corporations have joined the newly established IBMTR/ABMTR Corporate Membership Program (see above listing). The annual membership program provides member organizations with informational materials on blood and bone marrow transplantation developed by the IBMTR/ABMTR Information Resource Service.

The program includes subscriptions to the *Statistical Center Report on Survival Statistics for Blood and Marrow Transplants*, *IBMTR and ABMTR Newsletters*, the worldwide *IBMTR/ABMTR Directory of Bone Marrow Transplant Teams*, and the *IBMTR/ABMTR Summary Slides on State-of-the-Art in Blood and Marrow Transplantation* as well as invitations to our meetings and educational forums and access to the IBMTR/ABMTR databases for simple analyses. These resources are useful for marketing managers, medical directors, research directors, product managers, case managers or transplant coordinators.

For additional information on the Corporate Membership Program, please contact Susan Ladwig, Associate Director of Development ☎ (414) 456-8363, Fax: (414) 266-8471.

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National and International Presentations on Breast Cancer Using ABMTR Data November, 1995 - October, 1996

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Columbian Society for Oncology — Cali, Columbia
W.P. Vaughan: Advances in autologous and allogeneic BMT

Meeting of the Ecuador National Cancer Institute — Quito, Ecuador
W.P. Vaughan: Advances in BMT

December 1995

American Society of Hematology — Seattle, USA
P.A. Rowlings: Prognostic factors in autotransplants for metastatic breast cancer

January 1996

1996 IBMTR/ABMTR Participants' Meeting — Keystone, USA
K. Antman: Autotransplants for breast cancer

Keystone Symposium on Blood Cell and Bone Marrow Transplants — Keystone, USA
M.M. Horowitz: Analyzing transplant outcomes: comparison with other therapies
J.O. Armitage: Do autotransplants uniquely cure cancer?
R.P. Gale: How do autotransplants cure cancer?
K. Antman: Breast cancer workshop

February 1996

Blue Cross and Blue Shield Technology Center Forum — Chicago, USA
M.M. Horowitz: Outcomes of autologous transplants for breast cancer

March 1996

4th International Symposium on Blood Cell Transplantation — Adelaide, South Australia
K.A. Antman: Blood cell transplants for breast cancer

Association of Cancer Executives — Philadelphia, USA
R.O. Dillman: Update on autologous BMT

22nd Annual Meeting of the European Group for Blood & Marrow Transplantation — Vienna, Austria
M.M. Horowitz: Challenges in using observational data to compare transplant and non-transplant treatment

April 1996

First South American Transplantation Meeting — Buenos Aires, Argentina
P.A. Rowlings: Autotransplant for metastatic breast cancer

May 1996

American Society of Clinical Oncology — Philadelphia, USA
J.K. Erban: Effect of legislation mandating coverage for BMT for breast cancer

Experimental and Clinical Approaches in Oncology: Approaching the 21st Century — Teaneck, USA
M.M. Horowitz: Use of blood and marrow transplant in cancer treatment

Societat Catalana de Hematologia — Barcelona, Spain
A. Julia: Indications of transplantation

June 1996

Advances in Haematology — London, UK
M.M. Horowitz: Use of blood and marrow transplantation in cancer treatment

August 1996

8th International Symposium on Autologous Marrow and Blood Transplantation — Arlington, USA
P.A. Rowlings: ABMTR results
P.A. Rowlings: Clinical studies in metastatic disease

September 1996

Meeting of the American Academy of Insurance Medicine — Kansas City, USA
M.M. Horowitz: Outcome of blood and marrow transplantation

October 1996

Oncology Nursing Conference 1996 — Santo Domingo, Dominican Republic
C. Meneghetti: High dose chemotherapy and autologous BMT for breast cancer treatment

November 1996

Second Uruguayan Congress on BMT and PBSC Transplants — Montevideo, Uruguay
G. Milone: Advances in breast cancer treatment: BMT results

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Gomez Rodolfo	Universidad de Antioquia, Medellin, Colombia, S.A.
Ruben A. Saez	H. Lee Moffitt Cancer Center, Tampa, FL
Michael W. Schuster	North Shore University Hospital, Manhasset, NY
Leonard S. Sender	Children's Hospital of Orange County, Orange, CA
Thomas C. Shea	Univ of North Carolina at Chapel Hill, Chapel Hill, NC
Elizabeth J. Shpall	University Hospital, Denver, CO
Gary L. Spitzer	Intermountain Healthcare, Inc, Salt Lake City, UT
Edward A. Stadtmauer	Univ of Pennsylvania Hospital, Philadelphia, PA
Martin S. Tallman	Northwestern University, Chicago, IL
Charles W. Taylor	Univ of Arizona, Tucson, AZ
Robert F. Taylor	St. Luke's Medical Center, Milwaukee, WI
Luen Bik To	Hanson Centre for Cancer Research, Adelaide, SA, Australia
Linda T. Vahdat	Columbia University, New York, NY
Marlies E.H.M. Van Hoef	IBMTR/ABMTR, Medical College of Wisconsin, Milwaukee, WI
William T. Vaughan	Univ of Alabama at Birmingham, Birmingham, AL
B. Barry Weinberger	LSU Medical Center - Shreveport, Shreveport, LA
Stephanie F. Williams	The Univ of Chicago Medical Center, Chicago, IL
John R. Wingard	Emory University School of Medicine, Atlanta, GA
Jane N. Winter	Northwestern University, Chicago, IL
Steven N. Wolff	Vanderbilt University, Nashville, TN

Rec'd 1/11/2000

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MARYLAND 21702-5012

REPLY TO
ATTENTION OF:

MCMR-RMI-S (70-1y) 4 Jan 00

MEMORANDUM FOR Administrator, Defense Technical Information Center, ATTN: DTIC-OCA, 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for the attached Grants. Request the limited distribution statements for Accession Document Numbers listed be changed to "Approved for public release; distribution unlimited." This report should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Judy Pawlus at DSN 343-7322 or by email at Judy.Pawlus@amedd.army.mil.

FOR THE COMMANDER:

PHYLIS M. RINEHART
Deputy Chief of Staff for
Information Management

'95-1-5002 AD-B224543

completed 1-13-00 cn